

REMARKS

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, Claims 92, 94, 96, 98-101, 105, 106 and 109 will remain pending in the application. Claims 1-91, 93, 95, 97, 102-104, 107-108 and 110-114 have been canceled. Claims 92, 96, 100 and 109 have been amended. These changes do not introduce new matter, and their entry is respectfully requested.

In the Office Action of April February 19, 2003, the Examiner set forth a number of grounds for objection and rejection. These grounds are addressed individually and in detail below.

Claim objections

Claim 109 stands objected for improper grammar. Applicants have amended Claim 109 to avoid the use of "and/or" in the claim. This ground of objection has been obviated.

Rejections Under 35 U.S.C. § 112, first Paragraph

Written description

Claims 92-99, 107, and 109-114 stand rejected under 35 U.S.C. §112, first paragraph, for lack of written description support in the originally filed specification for reasons set forth on pages 2 and 3 of the Office Action. With regard to Claims 92-99 and 109-114, the Examiner alleges that the specification only support a method or a pharmaceutical composition for treating hemophilia B with rAAV particles containing Factor IX coding sequence.(see page 2, last paragraph and page 3, first paragraph of the Office Action).

Applicants have amended independent Claims 92 and 109 to restrict the present invention to the treatment for hemophilia B with rAAV particles containing Factor IX coding sequence, which is supported at page 13, lines 9-14, page 18, line 29 to page 19, line 16 of the present

specification.

The Examiner also alleges that there is no general teaching of including an IVS or splice donor or acceptor site, as claimed in Claims 107 and 109-114. Applicants respectfully disagree in that the specification teaches an IVS or splice donor or acceptor site at least on page 33, lines 9-10. However, in the interest of expediting the prosecution of this case, Applicants have amended the claims consistent with the Examiner's suggestion.

Applicants have canceled Claim 107. Independent Claim 109 has been amended to delete the term "an IVS", "or splice donor" and "or acceptor site".

The Examiner further alleges that claims 109-114 fail to recite any relationship between the structure gene, the promoter, and the enhancer.

Applicants have amended independent Claim 109 to better define the relationship between the structure gene and a regulatory element. The amended Claim 109 reads " A pharmaceutical composition for treating hemophilia B comprising (a) recombinant adeno-associated virus (rAAV) particles consisting essentially of AAV terminal repeats flanking an MFG promoter, a polynucleotide encoding Factor IX operably linked to the MFG promoter, a bovine growth hormone polyA sequence, and (b) a pharmaceutically acceptable carrier." The support for the amended Claim 109 can be found, for example, on pages 24-26, 31-32 and Fig. 6 of the present specification.

Therefore, the amendment of Claims 92 and 109 and the cancellation of Claim 107 completely addresses the stated grounds of rejection. The rejection of Claims 92-99, 107, and 109-114 for lack of written description should be withdrawn.

Enablement

Claims 92-114 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement for the reasons set forth on pages 3-13 of the Outstanding Office Action. The Examiner alleges

that Claims 92-114 are enabled only to those embodiments shown in the specification, such as the rAAV consists of terminal repeats flanking in order an MFG promoter, a Factor IX coding sequence, and bovine growth hormone poly A sequence . (See page 3, last paragraph and page 4, first paragraph of the Office Action).

Applicants disagree with the examiner's interpretation of the scope of the invention taught by the instant application. However, in the interest of furthering prosecution of this case, Applicants have amended independent Claims 92, 100 and 109 to restrict the present invention for the treatment of hemophilia B. Applicants further amended Claims 92, 100 and 109 to direct the rAAV particles consisting of AAV terminal repeats flanking a viral promoter (Claim 92) or MFG (Claims 100 and 109), a polynucleotide encoding Factor IX operably linked to the viral promoter, and bovine growth hormone polyA sequence.

Therefore, it is believed that the specification, at the time the application was filed, taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

Finally, the examiner interpreted Claims 100-108 as being implicitly directed to gene therapy and alleges that the implied use of this method to evaluate AAV as a suitable gene therapeutic vector does not meet the utility requirement. The Examiner's contention is respectfully traversed.

In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101. (See In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); see also MPEP, 2107.02 IIIA).

In the present case, it is well understood by one skilled in the art at the time of the invention that rAAV is one of the most promising viral vector for introducing a foreign gene into a mammalian cell. Such a vector can be used not only for gene therapy purpose, but also as a tool to

study the effect of an exogenous gene product on normal cellular function or disease etiology.

This is evidenced by hundreds of scientific publications on rAAV vectors before the time of the invention, as well as dozens of patent applications filed before the time of the invention.

Moreover, special care should be taken when assessing the credibility of an asserted therapeutic utility for a claimed invention. In such cases, a previous lack of success in treating a disease or condition, or the absence of a proven animal model for testing the effectiveness of drugs for treating a disorder in humans, should not, standing alone, serve as a basis for challenging the asserted utility under 35 U.S.C. 101. (MPEP 2107.02 IIIB).

Applicant has demonstrated effective *in vivo* expression of Factor IX in immune-deficient and immune-competent mice. It is well accepted that data generated using *in vitro* assays, or from testing in an animal model, or a combination thereof will be sufficient to establish therapeutic or pharmacological utility (MPEP, 2107.03 III). Accordingly, Applicant respectfully submit that the present invention has satisfied the 35 U.S.C. 101 utility requirement.

Taken together, it is believed that this ground of rejection has been obviated, and therefore, the rejection under 35 U.S.C. 112 first paragraph should be withdrawn.

Rejections Under 35 U.S.C. § 112, second Paragraph

Claims 96, 103, 107, 112 and 113 stand rejected under 35 U.S.C. 112 second paragraph for the reasons set forth on pages 13 to 14 of the Office Action.

Applicants have canceled Claims 103, 107, 112 and 113. Claim 96 has been amended to replace the term "the MFG promoter" with "a MFG promoter". Accordingly, it is believed that this ground of rejection has been obviated, and may properly be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 100, 101, 104 and 105-107 stand rejected under 35 U.S.C. 102(e) as being anticipated by Srivastava et al. (US 2001/0051611 A1) for the reasons set forth on pages 14 to 15 of the Office Action. Claims 104 and 107 have been canceled, and independent Claim 100 has been amended. Accordingly, Applicants respectfully traverse the rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. Verdegaal Bros. v. Union Oil Co. Of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. Scripps Clinic Research & Foundation v. Genentech Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

In this case, independent claim 100 is directed to a method of expressing a Factor IX protein in a mammal, comprising: administering recombinant adeno-associated virus (rAAV) particles to a mammalian liver cell, wherein said rAAV particles consist essentially of AAV terminal repeats flanking a MFG promoter, a polynucleotide encoding Factor IX operably linked to said MFG promoter, and a bovine growth hormone polyA sequence, and wherein following infection of said mammalian cell, Factor IX protein is expressed in the liver.

In contrast, Srivastava describes methods for selectively expressing therapeutic molecules in the liver. Srivastava neither describes the MFG promoter, nor mentions the specific viral construct as claimed in the present invention. Accordingly, Srivastava does not anticipate the present invention because it does not contain all of the elements of claim 100. Applicants further

submit that dependent claims 101, 105 and 106 are not anticipated by Srivastava because they depend from claim 100.

Thus, the grounds for this rejection have been obviated and withdrawal of the 35 U.S.C. 102(e) rejection is respectfully requested.

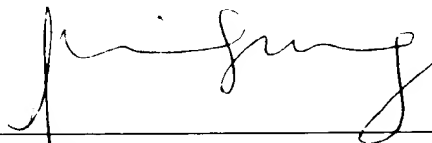
CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to contact Ping Wang, M.D. (Reg. No. 48,328) at the telephone number listed below.

Respectfully submitted,

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**Scripps Clinic & Research Foundation
v.
Genentech Inc.**

United States Court of Appeals, Federal
Circuit.

Nos. 89-1541, 89-1542, 89-1543, 89-1646 and
89-1647.

Decided March 11, 1991.

PATENTS

**[1] Patentability/Validity - Specification -
In general (§115.1101)**

Open-ended claims are not inherently improper; rather, their appropriateness depends upon particular facts of invention, disclosure, and prior art, and they may be supported if there is inherent, albeit not precisely known, upper limit and if specification enables one of skill in art to approach that limit.

**[2] Infringement - Defenses - Fraud or
unclean hands (§120.1111)**

**JUDICIAL PRACTICE AND
PROCEDURE**

**[3] Procedure - Summary judgment - In
general (§410.3301)**

Fact that both parties moved for summary judgment does not of itself establish that no disputed issue of fact exists and thus does not require that summary judgment be granted.

PATENTS

**[4] Practice and procedure in Patent and
Trademark Office - Reissue - Error
without deceptive intent (§110.1303)**

Error of law is not excluded from class of error subject to correction in accordance with reissue statute, 35 USC 241, and, although attorney error is not open invitation to reissue in every case in which it may appear, purpose of statute is to avoid forfeiture of substantive rights due to error made without intent to deceive; statutory standard of reissuable error is objective, and does not require

proof of subjective state of mind, nor does statute require showing that error in claiming product could not have been avoided, and thus inventors who established that they had claimed less than they had right to claim, that they had done so in error, and that there was no deceptive intention are entitled to reissue.

**[5] Patentability/Validity - Anticipation -
In general (§115.0701)**

**JUDICIAL PRACTICE AND
PROCEDURE**

**Procedure - Summary judgment - Patents
(§ 410.3303)**

Anticipation is question of fact, and finding of anticipation on motion for summary judgment requires federal district court to determine that no facts material to question are disputed, or that, even if all material factual inferences are drawn in favor of non-movant, there is no reasonable basis on which non-movant can prevail.

***1002 [6] Patentability/Validity -
Anticipation - In general (§115/- 7-1)**

Use of extrinsic evidence to explain reference's disclosure is sometimes appropriate, in order to show what reference meant to persons of ordinary skill in art, but is necessarily of limited scope and probative value, since finding of anticipation requires that all aspects of claimed invention were already described in single reference, and such finding would not be supportable if it is necessary to prove facts beyond those disclosed in reference in order to meet claim limitations; if it is necessary to reach beyond boundaries of single reference to provide missing disclosure of claimed invention, proper ground is not anticipation under 35 USC 102 but obviousness under 35 USC 103.

**[7] Patentability/Validity - Anticipation -
Prior publication (§ 115.0705)**

**JUDICIAL PRACTICE AND
PROCEDURE**

Procedure -- Summary judgment -- Patents
(§ 410.3303)

Federal district court erred by granting summary judgment that claims were invalid for anticipation, based upon subject matter described in prior publication, since apparent inconsistencies among three declarations filed by publication's author raise questions of credibility and weight and thus were improperly resolved on summary judgment, and since, in patent cases, questioning by affidavit is disfavored and is inadequate substitute for trial with witnesses, who are subject to examination and cross-examination in presence of decision-maker.

PATENTS

[8] Patentability/Validity -- Specification -- Best mode (§ 115.1107)

Compliance with best mode requirement is question of fact, and invalidity for failure of compliance requires proof by clear and convincing evidence that inventor knew of, and concealed, better mode of carrying out invention than was set forth in specification.

[9] Patentability/Validity -- Specification -- Best mode (§ 115.1107)

Failure of inventor, of claims for process of purifying blood clotting factor VIII:C, to voluntarily place in depository antibody which was used in carrying out claimed process is not sufficient to warrant finding of invalidity for failure to comply with best mode requirement, since Patent and Trademark Office did not require such deposit during examination of patent either initially or on reissue, since no protestor raised issue of deposit in connection with reissue application, and since failure to make deposit voluntarily cannot constitute legal or factual basis for patent invalidity.

[10] Infringement -- Doctrine of equivalents -- Reverse equivalents (§ 120.0703)

Federal district court erred by granting summary judgment of infringement of claims for process of purifying blood clotting factor VIII:C, in view of questions

of scientific and evidentiary fact raised by accused infringer that could produce sufficient ground for invoking doctrine of reverse equivalents.

[11] Infringement -- Defenses -- Fraud or inequitable conduct (§ 120.1111)

Reference which was considered by examiner cannot be deemed to have been withheld by applicant even if examiner discovered it "on his own."

[12] Practice and procedure in Patent and Trademark Office -- Prosecution -- Duty of candor -- In general (§ 110.0903.01)

Infringement -- Defenses -- Fraud or inequitable conduct (§ 120.1111)

Applicant has absolute right to decline to do work suggested by Patent and Trademark Office, and to withdraw claims presented for examination, without incurring liability for inequitable conduct.

[13] Infringement -- Construction of claims (§ 120.03)

Patent construction -- Claims -- Process (§ 125.1309)

Correct reading of product-by-process claims, for infringement purposes, is that they are not limited to product prepared by process set forth in claims, since, for purposes of determining patentability, product is not limited by process stated in claims, and since claims must be construed in same way for validity and for infringement.

Particular patents -- Chemical -- Blood clotting factor

4,361,509 (Re. 32,011), Zimmerman and Fulcher, ultrapurification of Factor VIII using Monoclonal antibodies, summary judgment of invalidity and infringement reversed.

Appeal from the U.S. District Court for the Northern District of California, *1003 Schwarzer, J.: 3 USPQ2d 1481, 6 USPQ2d 1018, 11 USPQ2d 1187, and 12 USPQ2d 1157.

Consolidated patent infringement actions filed by Scripps Clinic & Research Foundation, Revlon Inc., and Rorer Group Inc. against Genentech Inc. and

Miles Inc., and against Chiron Corp. From federal district court decision granting summary judgment on issues of invalidity and infringement, plaintiffs and Genentech cross-appeal. Affirmed in part, reversed in part, vacated in part, and remanded.

William S. Feiler, of Morgan & Finnegan, New York, N.Y. (Eugene Moroz, Patricia S. Rocha, and Bruce A. Pokras, of Morgan & Finnegan, with him on briefs; Stephen V. Bomse, of Heller, Ehrman, White & McAuliffe, San Francisco, Calif., of counsel, for plaintiffs-appellants.

James W. Geriak, of Lyon & Lyon, Los Angeles, Calif., (Douglas E. Olson, Bradford J. Duft, and Karol M. Pessin, of Lyon & Lyon, Los Angeles; Thomas J. Morgan and Melvin Blecher, of Lyon & Lyon, Washington, D.C., with him on briefs, for Genentech.

Arnold Sprung, of Sprung, Horn Kramer & Woods, (Nathaniel D. Kramer and Alan J. Grant of Sprung, Horn, Kramer & Woods, with him on brief), New York, N.Y., for Miles Inc.

William L. Anthony, of Townsend & Townsend, (Noemi C. Espinosa, of Townsend & Townsend, of counsel), Palo Alto, Calif., for Chiron Corp.

Before Markey [FN*] and Newman, circuit judges, and Beer, district judge. [FN49]

Newman, J.

This litigation concerns a substance called human Factor VIII:C, a complex protein that occurs naturally in normal blood and is essential to the clotting of blood. The patent in suit, United States Reissue Patent No. 32,011 (the "R'011" patent), is entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies", inventors Theodore S. Zimmerman and Carol A. Fulcher. Assigned to Scripps Clinic and Research

Foundation, it was licensed exclusively to Revlon, Inc. Subsequent to the filing of this suit Revlon sold its interest to Rorer Group, Inc.

By appeal and cross-appeal, the parties [FN1] raise various issues of patent validity and enforceability, infringement and inducement to infringe, and reissue law and practice, all of which were decided on motions for summary judgment. Each side challenges the decision of certain issues adverse to it, and the final judgment based thereon. [FN2]

The Invention

Factor VIII:C, called the clotting or procoagulant factor, is found in all mammals, although it differs among species. It has been the subject of extensive scientific research, over many years. At the time the claimed invention was made, it was known that human Factor VIII:C is a complex protein produced by the Factor VIII:C gene and secreted into the blood stream. It occurs in normal blood plasma (plasma is the fluid fraction of blood) at a concentration of about 200 nanograms per milliliter. The total protein content of plasma is about 70 milligrams (0.070 gram) per milliliter; since a nanogram is one billionth of a gram, the total protein in plasma is 350,000 times greater than the Factor VIII:C protein in plasma. Most of the problems faced by researchers attempting to isolate Factor VIII:C were due to the amount and nature of the other proteins in the plasma.

It was known that in normal blood Factor VIII:C exists in complex association with another protein, named the "von Willebrand factor" or Factor VIII:RP (RP means "related protein"). The weight ratio of Factor VIII:C to Factor VIII:RP in normal blood is about 1:100.

*1004 Before the invention here at issue was made, scientists had succeeded in concentrating the Factor VIII:C in

plasma. This concentrate has been used to replace transfusions of whole blood in the treatment of hemophilia. The process was expensive and, because of the large volume of whole blood needed as starting material, the possibility of contamination and disease from impurities in the source blood, the large amount of extraneous plasma proteins in the concentrate, and the large volume of concentrate that still had to be administered to the patient, there has been a continuing search for improvement. The record reflects the difficulties, over decades of research, in isolating and studying Factor VIII:C. Scripps reports that Genentech's scientists had been working in the field and had not isolated human Factor VIII:C in sufficient purity and amount to conduct successful characterization experiments.

At the Scripps Clinic & Research Foundation, Dr. Zimmerman and Dr. Fulcher were studying Factor VIII:C from human and porcine blood. These scientists succeeded in isolating and, for the first time, characterizing Factor VIII:C, by a process of chromatographic absorption of the Factor VIII:C complex using monoclonal antibodies specific to Factor VIII:RP, followed by separation of the Factor VIII:C. [FN3] Monoclonal antibodies are produced by the cloned copies of a single hybridoma cell. A hybridoma is a hybrid cell that is immortal: that is, it does not die as do normal cells, but continues to reproduce clones that in turn produce a specific antibody. As described in the R'011 patent, the hybridoma was made by fusing a mouse spleen cell that produced the desired antibody to Factor VIII:RP, with a mouse cancer cell, which contributed the immortality. The patent describes the method of assay for clones producing antibodies to VIII:RP, their isolation, and preparation of the monoclonal antibodies for use as the immunoadsorbent.

The claimed process whereby the Factor VIII:C/VIII:RP complex is separated from

the other materials in blood, followed by separation of the VIII:C from the VIII:RP, is described in the R'011 patent and was summarized by Scripps as follows:

The first step involves the application of a solution containing Factor VIII complex (Factor VIII:C/Factor VIII:RP) to a column packed with agarose beads. Attached to the beads is a monoclonal antibody to Factor VIII:RP. The monoclonal antibody binds and immobilizes the Factor VIII:RP part of the Factor VIII complex while the non-Factor VIII materials simply pass through the column. A calcium salt solution is then applied to break the bond between the Factor VIII:C and the Factor VIII:RP. The Factor VIII:C is eluted from the column while the Factor VIII:RP remains bound to the antibody.

The procedure produces purified but dilute Factor VIII:C:

After this first step the Factor VIII:C is highly purified, but dilute. A second step to concentrate the Factor VIII:C solution may then be performed. This involves absorbing the Factor VIII:C on an aminohexylagarose column. The Factor VIII:C on the aminohexyl column is then eluted with a very small amount of calcium salt solution, resulting in a highly concentrated solution of highly purified Factor VIII:C.

The potency and activity [FN4] of the fractions obtained by this technique were summarized by Scripps as follows:

When the Factor VIII:C is eluted from either type of column it is collected serially in a number of small, individual portions called "fractions." When the Factor VIII:C is eluted from the monoclonal antibody column, for example, the initial fractions will have little VIII:C. The VIII:C increases as the Factor VIII:C is released. After the majority of Factor VIII:C has been released, the later fractions will contain decreasing amounts.

Table I in the Zimmerman patent contains an analysis of two individual fractions. *1005 Patent Fraction 3 has a potency of 1172 units/ml and a specific activity of 2294 units/mg. Patent Fraction 4 is from another experiment and has a potency of 545 units/ml and a specific activity of 2370 units/mg.

Issues raised in this litigation concern purified Factor VIII:C and the reliability and reproducibility of the process, as these aspects relate to the validity, enforceability, and infringement of the R'011 patent claims.

The Claims

The claims in suit are product-by-process claims 13, 14, 17, 18, and 34, and product claims 24-29. Claim 13 is representative of the product-by-process claims:

13. Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.

Claim 1 is:

1. An improved method of preparing Factor VIII procoagulant activity protein comprising the steps of

(a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,

(b) eluting the VIII:C,

V(c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,

(d) eluting the adsorbed VIII:C, and

(e) recovering highly purified and concentrated VIII:C.

Product claims 24-29 were added by reissue, and are the focus of most of the controversy:

24. A human VIII:C preparation having a potency in the range of 134 to 1172 units per ml, and being substantially free of VIII:RP.

25. A human VIII:C preparation of claim 24, wherein the VIII:C concentration is at least 160,000 fold purified relative to VIII:C in plasma. [FN5]

26. A human VIII:C preparation of claim 24, wherein the ratio of VIII:C to VIII:RP is greater than 100,000 times the ratio in plasma.

27. A human VIII:C preparation of claim 24, wherein said VIII:C is isolated from VIII:C/VIII:RP and 90-100 percent of the VIII:RP has been removed.

V28. A human VIII:C preparation having a specific activity greater than 2240 units/mg.

29. A human VIII:C preparation of claim 28 wherein the potency is in the range of 134 to 1172 units/ml.

Summary Judgment

Summary judgment is a useful procedural tool whereby an unnecessary trial is avoided when there are no material facts in dispute. However, summary proceedings are not intended to substitute for trial when it is indeed necessary to find material facts. *Meyers v. Brooks Shoe, Inc.*, 912 F.2d 1459, 1461, 16 USPQ2d 1055, 1056 (Fed.Cir.1990) ("the factual dispute should be reserved for trial"). A factual question is material if a reasonable jury could return a verdict for the non-moving party based at least in part on its determination of the factual question. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the opponent of the motion, *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 473 (1961), and doubts resolved in favor of the

opponent. *Cantor, dba Selden Drugs Co. v. Detroit Edison Co.*, 428 U.S. 579, 582 (1976).

A motion for summary judgment must be supported with a sufficient showing to establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The burden of establishing entitlement to summary disposition is with the movant, with due consideration to the burden of proof. *Id.* When a sufficiently supported motion has been submitted, the burden of coming forward and showing that there is a genuine issue of material fact shifts to the non-movant. The Court has observed that "all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Anderson*, 477 U.S. at 249 (quoting *First National Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 288-289 (1968)). However, "[i]f the evidence is merely colorable, or is not significantly probative, summary judgment may be granted". *Anderson*, 477 U.S. at 249-50 (citations omitted).

*1006 Scripps and Genentech both argue that certain issues that were decided summarily against each of them were not resolvable on summary judgment in favor of the other, if Rule 56 were correctly applied. We have concluded that the district court was correct in its determination, as to some of the issues in suit, that there were no questions of material fact; but not for all issues. For those issues that could indeed be decided summarily, we have reviewed the decision for correctness as a matter of law. For those issues on which summary judgment was inappropriately granted, we have reversed the grant and remanded for trial.

I

Inequitable Conduct and Enablement

On the basis of statements that the inventors made to the reissue examiner in connection with prosecution of the newly added product claims, issued as claims 24-29 of the R'011 patent, the district court granted Genentech's motion for summary judgment of unenforceability of the claims based on inequitable conduct.

Although the court did not hold the claims invalid for lack of enablement, the issues of enablement and inequitable conduct were intertwined. The "enablement" requirement is set forth in Title 35 as follows:

35 U.S.C. § 112 ¶ 1. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....

During prosecution of the reissue application the patent examiner had raised various questions under § 112, relating to the purity of the Factor VIII:C that was the subject of the proposed product claims. Communications from the inventors covered such matters as the presence of fibrinogen and fibronectin and their removal by those skilled in the art; variations in chromatographic purification results; and the determination of purity using SDS-gels. The examiner requested a showing of the mathematical relationship between specific activity and fold purification, and other data, which the inventors provided.

The reissue examiner's objection to the scope of the product claims was withdrawn on the inventors' response that they had obtained human Factor VIII:C at "levels closely approaching the theoretical limit". The inventors explained that the difference in fold purification of about 169,000 shown in Table I, and their calculation of the theoretical value of 357,000-fold, was 2-fold, from which the

inventors stated that the "specification teaches those skilled in the art the production of essentially pure VIII:C." They explained that the removal of any remaining fibrinogen and fibronectin was within the skill of the art, when these impurities were identified. The examiner, apparently satisfied with the inventors' answers, [FN6] granted the reissue application with the added product claims as amended.

[1] The inventors distinguished the case of *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), which held the open-ended claims there presented unpatentable for lack of enablement of "future compositions having potencies far in excess of those obtainable from his teachings plus ordinary skill". *Id.* at 839, 166 USPQ at 24. Open-ended claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art. They may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit. *See Fisher, supra.* \$MAJI While Genentech argues that the issue is whether the inventors misrepresented the purity of their Factor VIII:C, Scripps points out that the claims do not require 100% pure VIII:C. The product-by-process claims all refer to "highly purified and concentrated" VIII:C, and the product claims contain limitations that are met by less than 100% pure VIII:C: for example, that the VIII:C is "at least 160,000 fold purified relative to VIII:C in plasma" (claim 25), that "the ratio of VIII:C to VIII:RP is greater than 100,000 times the ratio in plasma" (claim 26), that the VIII:C product has a potency of 134-1172 units/ml (claim 24) or a specific activity of over 2400 units/mg (claim 28), and is substantially free of VIII:RP (claims 24-27). *1007 Indeed, the district court did not find that all these claim limitations depended on the criticized representations about purity that were

made to the examiner. However, the court found that the inventors' statements about the purity of the product were unsupported by evidence, and on this basis adjudged all the claims unenforceable for inequitable conduct.

The court referred to a Declaration by Drs. Zimmerman and Fulcher, during prosecution of the reissue application, that "we have achieved purified VIII:C at levels very near what we believe to be the theoretical values with the claimed process." The court found that "Drs. Zimmerman and Fulcher made crucial factual assertions, for the purpose of reversing the Examiner's initial rejection of the open-ended purity claims, for which they had no factual support." The court stated at the hearing that the inventors made statements about purity for which they did not have evidence:

THE COURT: ... and without implying improper motives it is an issue [purity] on which the inventors did not seem to have evidence but without evidence they created the--well, you say they made a square statement saying that almost always will you get pure VIII:C when, in fact, they didn't know that you would almost always get pure VIII:

The district court expressed its concern about the inventors' knowledge of the reliability of the process:

THE COURT: Mr. Feiler, I'm not questioning that they got pure C, they have gotten lots of pure C. What they did not know was what is the probability of getting VIII:C every time you run one of these columns. What percentage of the fractions that come out will be pure VIII:C. They just didn't know.

This reasoning is reflected in the court's finding:

[T]he undisputed evidence shows that (1) only some of the fractions appeared to be free of fibronectin while others were not,

(2) the inventors were unable to quantify how much fibronectin the stream of the product from the column contained, and (3) the fraction on which the patent application (Table I) was based contained up to 50% fibronectin.

Scripps, 707 F.Supp. at 1557, 11 USPQ2d at 1196.

Scripps stated that the inventors' statements to the examiner were justified, that the inventors believed them to be correct, that there was evidence before the district court that the inventors obtained gels showing essentially pure Factor VIII:C, and that the inventors obtained immunological tests showing no evidence of fibronectin or fibrinogen. Scripps argued that the inventors had the good faith belief that they had enabled the preparation of pure Factor VIII:C, and referred to evidence of contemporaneous correspondence from Dr. Zimmerman to other scientists that "We believe that purification of the human VIII:C is essentially complete". There were declarations filed with the district court, of Dr. Katzmann (a scientist at the Mayo Clinic) and Dr. Hrinda (a scientist at Rorer), that the inventors had obtained essentially pure Factor VIII:C. Dr. Katzmann also explained that Factor VIII:C activity can vary in samples having the same degree of purity; Genentech's data showed the same effect. There was deposition testimony on tests by Dr. Fulcher, showing no fibronectin.

Genentech asserts that the inventors deliberately withheld an analysis of the Table I material after the examiner requested it, and misrepresented that the impurities were "trace" when in fact the materials described in the specification contained 50% fibrinogen and fibronectin. Scripps responds that the requested analysis of the Table I material was indeed provided, that the examiner understood and was not misled by the inventors' statements about purity, that additional evidence showed that the

representations made to the examiner were scientifically correct, and that, in all events, the statements were made in good faith.

The district court placed substantial weight on Dr. Zimmerman's deposition testimony that "trace contaminants" fibrinogen and fibronectin remained, that he "did not have numbers for upper limits", and that "[i]t is a trivial matter to remove the fibrinogen and fibronectin once they have been identified". The court commented that "Dr. Fulcher in her deposition was unable to quantify [the term 'essentially pure'] or the term 'highly purified' ", and remarked that it is "impossible to extrapolate from one or several Laurells [tests of a fraction of the column stream] as to the degree of purity of the entire output". The court criticized these scientific facts as legal inadequacies.

*1008 [2] The materiality of a representation, and whether the representation was made with intent to deceive or mislead, are the two essential factual predicates to determination of inequitable conduct. *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 541, 16 USPQ2d 1622, 1624 (Fed.Cir.1990). The district court stated that the "three elements of inequitable conduct" are "material prior information, chargeable to applicant, not disclosed to the PTO". *Scripps*, 707 F.Supp. at 1557, 11 USPQ2d at 1196. Notably missing is the element of intent, essential as a matter of law to a ruling of inequitable conduct. See *Kingsdown Medical Consultants, Ltd., v. Hollister, Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed.Cir.1988). Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence. While Genentech argues that absence of reference by the court to intent does not mean that the court did not find intent, the court's remark that it was "without implying improper motives [to the inventors]" contravenes this argument.

Even were the inventors' statements concerning purity in error, a finding of disputed fact that is not appropriate on summary judgment, the absence of a finding of intent to deceive or mislead the examiner precludes summary judgment of inequitable conduct. *See KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1573, 228 USPQ 32, 35-36 (Fed.Cir.1985) (a disputed question of intent to deceive is not appropriate for summary resolution).

The grant of partial summary judgment of unenforceability of the R'011 claims for inequitable conduct is reversed.

[3] Scripps had filed a cross-motion for summary judgment on this issue. This does not, of itself, require adjudication in its favor. *United States v. Fred A. Arnold, Inc.*, 573 F.2d 605, 606 (9th Cir.1978); *accord*, *Cram v. Sun Insurance Office, Ltd.*, 375 F.2d 670, 673-74 (4th Cir.1967) ("The fact that both sides moved for summary judgment does not establish that there is no issue of fact and require that judgment be granted for one side or the other"). These disputed factual questions of materiality and intent, which depend on the assessment of scientific facts as well as on the credibility of witnesses, are not amenable to summary resolution. The issue is remanded for trial.

II

35 U.S.C. § 251

A

The R'011 patent is a reissue of Patent No. 4,361,509 ("the '509 patent"), granted on November 20, 1982. Genentech challenged the adequacy of the patentee's reason for seeking reissue, stating that this reason was insufficient in terms of 35 U.S.C. § 251. On this ground the district court granted Genentech's motion for partial summary judgment of invalidity of claims 17, 18, 24-29, and 34.

Although there were factual aspects

debated by the parties, they are not material to the question of the legal adequacy of the patentee's reason for requesting reissue. That is a question of law, and the facts material to that question were not in dispute. The matter could have been, and was, decided summarily. *See Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 662, 231 USPQ 649, 651 (Fed.Cir.1986) *cert. denied*, 480 U.S. 933 (1987) "These facts are not in dispute, though their legal significance is. Thus the basis on which the district court decided the question was amenable to summary judgment". However, the district court erred in its conclusion of law.

The reissue statute provides in part:

35 U.S.C. § 251. Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall ... reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application.... No new matter shall be introduced into the application for reissue.

In accordance with 37 C.F.R. § 1.175(a)(5) and (a)(3) the applicant for reissue must "specify[] the errors relied upon, and how they arose or occurred," and must "distinctly specify[] the excess or insufficiency in the claims"; and in accordance with 37 C.F.R. § 1.175(a)(6) the applicant must declare the absence of deceptive intention.

The principal error that the inventors sought to cure was the claiming of "less than [they] had a right to claim in the patent" due to the omission of product claims. The '509 patent contained only process and product-by- process claims. [FN7] In the reissue application inventors Zimmerman and Fulcher declared that

they had always viewed the Factor VIII:C product as their invention, pointing out that the '509 specification stated *1009 that it was an object of their invention to produce highly purified Factor VIII:C.

[4] An error of law is not excluded from the class of error subject to correction in accordance with the reissue statute. Although attorney error is not an open invitation to reissue in every case in which it may appear, *see In re Weiler*, 790 F.2d 1576, 1579, 229 USPQ 673, 675 (Fed.Cir.1986) ("not every event or circumstance that might be labeled 'error' is correctable by reissue"), the purpose of the reissue statute is to avoid forfeiture of substantive rights due to error made without intent to deceive. *See generally Ball Corp. v. United States*, 729 F.2d 1429, 1939 n. 28, 221 USPQ 289, 296 n. 28 (Fed.Cir.1984) (the reissue statute "is based on fundamental principles of equity and fairness").

When the statutory requirements are met, reissuance of the patent is not discretionary with the Commissioner; it is mandatory ("shall"). *See In re Handel*, 312 F.2d 943, 948, 136 USPQ 460, 464 (CCPA 1963) ("the whole purpose of the statute, so far as claims are concerned, is to permit limitations to be added to claims that are too broad or to be taken from claims that are too narrow").

Genentech does not dispute that error was made, and does not challenge the principle of the availability of product claims to the purified Factor VIII:C. Further, Genentech does not assert that the attorneys' initial view of the unavailability of product claims involved any deceptive intention. The district court, holding that there was insufficient reason for reissue, appeared to interpret § 251 as requiring a showing that the error in claiming the product could not have been avoided, in order to be eligible for cure. This is not the framework of the reissue statute.

The law does not require that no competent attorney or alert inventor could have avoided the error sought to be corrected by reissue. Failure of the attorney to claim the invention sufficiently broadly is "one of the most common sources of defects". *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed.Cir.1984), *cert. denied*, 469 U.S. 1209 (1985):

An attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects in patents. The fact that the error could have been discovered at the time of prosecution with a more thorough patentability search or with improved communication between the inventors and the attorney does not, by itself, preclude a patent owner from correcting defects through reissue.

Id. at 1519, 222 USPQ at 371.

Subjective intent is not determinative of whether the applicants erred in claiming less than they had a right to claim. *In re Mead*, 581 F.2d 251, 255, 198 USPQ 412, 416 (CCPA 1978). "Intent to claim" is not the criterion for reissue, and has been well described as "but judicial shorthand, signifying a means of measuring whether the statutorily required error is present." *In re Weiler*, 790 F.2d 1576, 1581, 229 USPQ 673, 676 (Fed.Cir.1986) (emphasis in original). The statutory standard of reissuable error is objective, and does not require proof of subjective state of mind:

Determining what protection [an inventor] intended to secure by [an] original patent for the purposes of § 251 is an essentially factual inquiry confined to the *objective* intent manifested by the original patent.

In re Rowand, 526 F.2d 558, 560, 187 USPQ 487, 489 (CCPA 1975) (emphasis in original).

On undisputed facts, the inventors established that they had claimed less than they had a right to claim, that they

had done so in error, and that there was not deceptive intention. The application for reissue fully complied with the statutory and regulatory requirements. [FN8]

As a matter of law, reissue claims 17, 18, 24-29, and 34 are not invalid on this ground. The grant of partial summary judgment is reversed. On remand, partial summary judgment shall be entered for Scripps on this ground.

B

The district court had also held the reissue product claims invalid for inadequate support in the specification for their open-ended scope, referring to changes that Drs. Zimmerman and Fulcher made in the text of the specification during the drafting process. For example, they changed "virtually pure" to "highly purified"; and inserted "largely" before "free of contaminants". This is an issue of enablement, which is not challenged by Genentech; but it also raises questions of claim interpretation in light of the specification. In view of the several disputed questions of material fact underlying these issues, see Part I *ante* and Part V *post*, summary judgment on this ground was improper, and the *1010 grant thereof is reversed. This issue, also, requires trial.

III

Anticipation

The district court held, on cross-motions for summary judgment, that "it had been proved by clear and convincing evidence" that claims 24, 26, and 27 were invalid for anticipation, 35 U.S.C. § 102(b), based on subject matter described in a 1979 dissertation by Robert B. Harris entitled "Isolation and Characterization of Low Molecular Weight, Non-Aggregated Antihemophilic Factor from Fresh Human Plasma".

A

[5] Anticipation is a question of fact. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619, 225 USPQ 634, 637 (Fed.Cir.), *cert. dismissed*, 474 U.S. 976 (1985). To make such finding on summary judgment, the court must determine that no facts material to the question are disputed; or that even if all material factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. *Cooper v. Ford Motor Co.*, 748 F.2d 677, 679, 223 USPQ 1286, 1288 (Fed.Cir.1984). The standard of proof that would have to be met at trial must be considered. *Anderson*, 477 U.S. at 257.

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed.Cir.1986); *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed.Cir.1984). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

[6] It is sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference. Such factual elaboration is necessarily of limited scope and probative value, for a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference. See *Studiengesellschaft Kohle, mbH v. Dart Industries, Inc.*, 726 F.2d 724, 727, 220 USPQ 841, 842 (Fed.Cir.1984) (although additional references may serve to reveal what a reference would have meant to a

person of ordinary skill, it is error to build "anticipation" on a combination of these references). If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground is not § 102 anticipation, but § 103 obviousness. Indeed, a publication on the Harris dissertation was included in the prior art statement filed by Scripps and was a cited reference under § 103.

B

In the summary judgment proceedings the parties filed three successive declarations of Dr. Harris, each explaining his dissertation. In the first declaration, filed by Miles, Inc., Harris stated that he isolated "a low molecular weight antihemophilic factor". In his second ("supplemental") declaration, filed by Scripps, Harris described this factor as not a naturally occurring substance, and of low specific activity:

6. The material I identified as low molecular weight antihemophilic factor (LMW-AHF) was not a naturally occurring substance. The material of my dissertation is the result of reacting plasma with a reducing agent called dithiothreitol (DTT) prior to purification. The reduced plasma is run through an initial purification step, and is then chemically reacted with radioactively labeled iodoacetamide (14C-IAA). This reduced and alkylated material was the LMW-AHF reported in my dissertation. After further purification, I obtained a maximum specific activity of 59.1 [units]/mg.

In the third Harris declaration, filed by Miles, Harris stated that his dissertation

accurately reports on my work in which I was able to, and did, obtain a human VIII:C preparation having a potency of 193 [units]/ml and being substantially free of VIII:RP, the ratio of VIII:C to VIII:RP being greater than 100,000 times the ratio in plasma.

The third Harris declaration was cited by the district court in support of its finding of anticipation.

The parties debate whether Harris' statement in his second declaration that his product was chemically changed from naturally occurring VIII:C, is contradicted by the statement in his third declaration that he obtained a human VIII:C preparation. Scripps also points out that neither the potency*1011 value nor the ratio of VIII:C to VIII:RP described in the third Harris declaration appears in the Harris dissertation. Nor does the gel pattern evidence on which the district court found that:

Harris also based his identification of his preparation upon sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) tests [the same tests used by Dr. Fulcher]. While Harris' gel patterns do not match the gel pattern found by Dr. Fulcher, there is no evidence that if he had VIII:C, it would necessarily have the gel pattern found by Dr. Fulcher.

Scripps, 707 F.Supp. at 1551 n. 6, 11 USPQ2d at 1190 n. 6. Further, this finding that human Factor VIII:C, if obtained by Harris, would not necessarily have the "fingerprint" gel pattern of Dr. Fulcher, was not simply an adverse factual inference, improper on summary judgment; it was a finding of scientific fact contrary to the evidence. This finding also appears to be inconsistent with the court's finding that Dr. Harris had obtained purified Factor VIII:C because he based his identification on the same tests and gel patterns taught by Zimmerman and Fulcher. Also contradicting the court's conclusion was Scripps' evidence that the human Factor VIII:C SDS-gels of the inventors, the defendants, and non-parties to the litigation were the same, and that Dr. Harris' gel patterns were different.

15. Neither is there any information from which to infer that the LMW-AHF

recovered in the experiment represented by Figure 9 was the subject of [the page 56] lyophilization and reconstitution experiment.

Scripps also states that the maximum potency that the dissertation disclosed was 10 units/ml. Even crediting Dr. Harris' assertion that the ratio of AHF (antihemophilic factor) to VWF (von Willebrand factor) may have been as high as 100,000:1, Scripps calculated that this would only increase the potency of the concentrated sample on Harris' page 56 to a maximum of 10.0 units/ml. A sample having the potency of 191.7 units/ml, the value found by the district court, was calculated by Scripps to have a theoretical ratio of no less than 1,917,000:1, over 19 times higher than that asserted by Dr. Harris in his dissertation. Scripps thus argues that the court's findings are contrary to the evidence. We need not decide the correctness of these calculations and their premises, for it is clear that these issues, on which there was conflicting evidence, were not subject to summary resolution.

[7] To the extent that apparent inconsistencies among the three Harris declarations raise questions of credibility and weight, whether of witness or of interpretation of scientific data, they were improperly resolved on summary judgment. *Agosto v. INS*, 436 U.S. 748, 756 (1977); *Poller*, 368 U.S. at 473. In patent cases, questions by affidavit is disfavored. See *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 473 (1961); *United States v. Fred A. Arnold, Inc.*, 573 F.2d 605, 606 (9th Cir.1978). Trial by document is an inadequate substitute for trial with witnesses, who are subject to examination and cross-examination in the presence of the decision-maker. *Sartor v. Arkansas Natural Gas Corp.*, 321 U.S. 620, 628 (1944).

Scripps also raised the question of whether the Harris dissertation was enabling and placed the purported

anticipatory teaching of purified Factor VIII:C in possession of the public. Scripps pointed out that data in Harris' third declaration, on which the court relied, do not appear in his dissertation or in any other reference. See *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed.Cir.1986), cert. denied, 482 U.S. 909 (1987) (anticipatory reference must be enabling); *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964). The need to consider this issue, on disputed factual premises, also negates the propriety of the grant of summary judgment based on anticipation.

The grant of partial summary judgment of invalidity of claims 24, 26, and 27 for anticipation by the Harris dissertation is reversed. The issue is not amenable to summary disposition, and is remanded for trial.

IV

Best Mode

The district court granted Genentech's motion for summary judgment that claims 13, 14, 17, 18, 24-29, and 34 are invalid for failure to comply with the "best mode" requirement of 35 U.S.C. § 112:

*1012 § 112. The specification shall ... set forth the best mode contemplated by the inventor of carrying out his invention.

[8] Compliance with the best mode requirement is a question of fact, and invalidity for failure of compliance requires proof by clear and convincing evidence that the inventor knew of and concealed a better mode of carrying out the invention than was set forth in the specification. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1369, 1379, 231 USPQ 81, 90 (Fed.Cir.1986), cert. denied, 480 U.S. 947 (1987).

The concealment asserted by Genentech relates to the es to the monoclonal antibodies that bind the Factor VIII

complex in the initial step of separation from plasma. Genentech did not dispute that the specification describes the inventors' preferred method of obtaining these monoclonal antibodies. The specification describes the process, starting with injection into mice of the commercial Factor VIII concentrate, to produce antibodies against Factor VIII:RP; the preparation of the hybridomas and their screening for the desired antibodies; and the method of evaluation of the antibody's ability to bind Factor VIII:RP in the presence of salt solution that disassociates Factor VIII:C. The specification describes the properties for which the antibodies were screened, viz. to obtain a monoclonal antibody to Factor VIII:RP, of the IgG class, which binds greater than 90% of the VIII:RP out of plasma or concentrate, and which remains bound to the VIII:RP during saline elution of Factor VIII:C.

None of this was criticized by Genentech. There was no charge of concealment of special manipulations, or undisclosed techniques. Genentech's argument is primarily that because of the laborious nature of the process of screening monoclonal antibodies, the inventors should have voluntarily placed in a depository and made available to the public the antibody to Factor VIII:RP designated 2.2.9, which was the first effective antibody obtained by Scripps' screening, and was used by Scripps in carrying out the claimed invention.

Scripps states that the procedures in the specification produce monoclonal antibodies having the characteristics set forth in the specification, that the process of obtaining these antibodies was fully disclosed, that the data in Table I are for the 2.2.9 antibody, and that the 2.2.9 antibody was not concealed. Scripps agreed that the 2.2.9 antibody was indeed the first that had the described properties, and states that three out of the first seven antibodies screened had these properties, all obtained by routine and

admittedly time-consuming procedures. It was not disputed that the inventors obtained the 2.2.9 antibody by following the procedures in the patent specification, and that these were the inventors' preferred procedures.

The district court found that the inventors concealed the 2.2.9 antibody, and that this antibody was the best mode of carrying out the invention. The court did not hold that deposit of the 2.2.9 antibody was required, although the court stated that a person of skill in the art would not have known "where to obtain it". The court made no other finding relating to concealment.

[9] A deposit was not required by the PTO during examination of either the '509 or the R'011 patents. See M.P.E.P. § 608.01(p)(C)(3). Nor does Genentech argue that deposit was obligatory. No protester raised the issue of deposit in connection with the reissue application. Although Genentech suggests that Scripps should have made a deposit voluntarily, failure to do so can not constitute legal or factual basis for patent invalidity.

Despite the extensive attorney argument, there were no material facts in dispute. There was no evidence by Genentech that the antibodies used by Drs. Zimmerman and Fulcher differed from those obtainable according to the process described in the specification. The laborious nature of this work was recognized in *Hybritech, supra*, and again in *In re Wands*, 858 F.2d 731, 737-38, 8 USPQ2d 1400, 1406-07 (Fed.Cir.1988). In *Wands* this court, considering the question of enablement, declined to require the deposit of antibody samples that could be obtained by screening following the procedures in the specification.

Genentech had argued to the PTO, in its Protest against the reissue application, that the process is "easily" carried out to produce "high affinity monoclonal antibodies":

[T]here are numerous references demonstrating the ease with which high affinity monoclonal antibodies could be obtained to Factor VIII:R[P].

In the context of best mode, on facts similar to those at bar, this court's holding in *Hybritech* settled the issue:

The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening and that the screening process is labor-intensive and time-consuming. *It is not plausible that this evidence amounts to proof of concealment of a best mode for screening or producing monoclonal antibodies *1013 for use in the claimed '110 process, and therefore we are of the firm conviction that the district court's finding that the best mode requirement was not satisfied is clearly erroneous.*

Hybritech, 802 F.2d at 1385, 231 USPQ at 94 (emphasis added). Applying *Hybritech* to the undisputed facts, a finding of concealment can not be supported. The claims were incorrectly held invalid on this ground.

As a matter of law, we reverse the grant of partial summary judgment that claims 13, 14, 17, 18, 24-29, and 34 are invalid for failure to meet the best mode requirement. We remand with instructions that partial summary judgment be entered for Scripps on this ground.

V

Infringement

The district court found the R'011 product claims 24, 25, 28, and 29 literally infringed, explaining that "Human factor VIII:C as claimed in the [product claims] therefore applies to any Factor VIII:C preparation, regardless of how produced, having the same material structural and functional characteristics as the plasma-

derived preparation." The court did not distinguish between plasma-derived and recombinantly-produced human Factor VIII:C. [FN9] Genentech does not challenge this ruling as applied to plasma-derived VIII:C.

A

Genentech appeals the district court's grant of Scripps' motion for summary judgment that the product claims are infringed by Genentech's recombinantly-produced human Factor VIII:C. Genentech states that the product claims should be construed, as a matter of law, to avoid infringement by recombinant VIII:C. Alternatively, Genentech argues that infringement is avoided by application of the reverse doctrine of equivalents. These two theories of non-infringement require different analytic approaches.

In "claim construction" the words of the claims are construed independent of the accused product, in light of the specification, the prosecution history, and the prior art. Of course the particular accused product (or process) is kept in mind, for it is efficient to focus on the construction of only the disputed elements or limitations of the claims. However, the construction of claims is simply a way of elaborating the normally terse claim language: in order to understand and explain, but not to change, the scope of the claims.

We described the workings of claim construction in *Tandon Corp. v. Int'l Trade Comm.*, 831 F.2d 1017, 1021, 4 USPQ2d 1283, 1286 (Fed.Cir.1987):

Claim interpretation is a question of law, having factual underpinnings. When the meaning of key terms of claims is disputed ... extrinsic evidence may be adduced including testimony of witnesses, and reference may be had to the specification, the prosecution history, prior art, and other claims.

Genentech argues that the term "a human VIII:C n VIII:C preparation" in the R'011 product claims should be construed as limited to the Factor VIII:C obtained by separation from plasma. In essence, Genentech argues that these claims should be construed as carrying an inherent process limitation, on the basis that Scripps did not invent human Factor VIII:C, or discover its structure, or its properties as the coagulant factor in blood, but simply the process of purifying it to a higher degree of purity than was heretofore available. However, Genentech also states that it is not challenging the propriety of product claims to Factor VIII:C; and it did not do so before the district court. While judicial attention has on occasion focused on the patentability of claims in this context, *see, e.g., In re Bergstrom*, 427 F.2d 1394, 166 USPQ 256 (CCPA 1970), Genentech, by conceding that the product claims were appropriately granted, presents inconsistent legal arguments. Genentech has not supported, as a matter of law, its requested claim construction.

B

The so-called "reverse doctrine of equivalents" is an equitable doctrine invoked in applying properly construed claims to an accused device. Just as the purpose of the "doctrine of equivalents" is to prevent "pirating" of the patentee's invention, *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 607, 608, 85 USPQ 328, 330, *reh'g denied*, 340 U.S. 845 (1950), so the purpose of the "reverse" doctrine is to prevent unwarranted extension of the claims*1014 beyond a fair scope of the patentee's invention.

The reverse doctrine of equivalents flows from the Supreme Court's statement in *Graver Tank* that an accused article may avoid infringement, even if it is within the literal words of the claim, if it is "so far changed in principle from a patented article that it performs the same or a similar function in a substantially

different way." 339 U.S. at 608-09, 85 USPQ at 330. Application of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, which in turn is determined in light of the specification, the prosecution history, and the prior art.

The record contained evidence of the properties of plasma-derived and recombinantly produced VIII:C, which was presented primarily by Scripps in connection with its proofs of infringement. There was deposition testimony that there were differences between VIII:C from plasma and VIII:C obtained by recombinant techniques; a Scripps' witness described the products as "apples and oranges", referring specifically to stability and formulations. The parties disputed, in connection with the summary judgment motions, the capabilities of the respective processes in terms of the purity and specific activities that were enabled for the respective products. The record on this point is extensive.

Genentech argues that its product is equitably seen as changed "in principle", particularly when viewed in the context of the prior art. Genentech asserts that the specific activities and purity that are obtainable by recombinant technology exceed those available by the Scripps process; an assertion disputed by Scripps, but which if found to be correct could provide—depending on the specific facts of similarities and differences—sufficient ground for invoking the reverse doctrine. These aspects were not discussed by the district court.

[10] The principles of patent law must be applied in accordance with the statutory purpose, and the issues raised by new technologies require considered analysis. Genentech has raised questions of scientific and evidentiary fact that are material to the issue of infringement. Consideration of extrinsic evidence is

required, and summary judgment is inappropriate. See *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673, 15 USPQ2d 1540, 1542 (Fed.Cir.1990).

The grant of summary judgment of infringement of claims 24, 25, 28, and 29 is reversed. The issue requires trial.

VI

Inducement to Infringe

The district court held that Genentech induced Cutter Laboratories to infringe claims 24, 25, 28, and 29 of the R'011 patent, 35 U.S.C. § 271(b), through the use of both plasma-derived and recombinant Factor VIII:C. The court held:

There is no question that Genentech delivered to Cutter materials found to have infringed, including recombinant and plasma-derived human Factor VIII:C, with the intent that Cutter itself would [develop recombinant Factor VIII:C].... There is also no doubt that Genentech intended Cutter to use plasma-derived Factor VIII:C manufactured by both Genentech and Cutter which has been found to infringe.

Scripps, 666 F.Supp. at 1394, 3 USPQ2d at 1493. The facts of the relationship between Genentech and Cutter were undisputed.

Genentech states that the district court made no specific finding of direct infringement by Cutter, a predicate to a finding of inducement to infringe. Cutter is a division of Miles, a defendant herein, and is subject to the district court's finding of infringement. Thus the court's ruling on inducement was correct, as a matter of law. Subject to our holding in Part V, the decision of the district court on this issue is affirmed.

VII

Inequitable Conduct based on the Meyer Abstract

Genentech appeals the district court's grant of summary judgment that Scripps did not engage in inequitable conduct, during examination of the application that led to the '509 patent, based on a reference authored by Meyer, Obert, Zimmerman, and Edgington entitled *Monoclonal Antibodies Specific for Factor VIII from Cellular Hybrids*, No. 395 ("the Meyer abstract").

The district court observed that the Meyer abstract was cumulative to the complete Meyer paper it summarized:

The Meyer abstract was also cited in a paper authored, *inter alia*, by Dr. Meyer herself that was submitted by Scripps to the PTO as reference RS.... In contrast to the Meyer abstract, which is only one paragraph long, reference RS is 27 pages in length and much more elaborate in its disclosure....

Scripps, 666 F.Supp. at 1399-1400, 3 USPQ2d at 1496. A reference that is simply *1015 cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct. *Halliburton Co. v. Schlumberger Technology Corp.*, No. 90-1191, slip op. at 9 (17 USPQ2D 1834) (Fed.Cir. Feb. 15, 1992).

[11] The Meyer abstract was before the patent examiner who, according to Genentech, discovered it "on his own". When a reference has been considered by the examiner, it is not controlling how it came to the examiner's attention. The complete Meyer paper, and several other references, cited the Meyer abstract. Genentech argues that Scripps should nonetheless have brought the Meyer abstract to the examiner's specific attention, in addition to having listed the complete Meyer paper in Scripps' prior art statement. When a reference was before the examiner, whether through

the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner.

Genentech presses the argument that the district court erred because the Meyer abstract was a "statutory bar", by which Genentech explains that it was published more than a year before the patent's filing date. Genentech does not explain how this was error, for the district court, like the PTO, treated as prior art both the 27-page Meyer paper and the Meyer abstract. Genentech's argument that the full paper "was not effective prior art" is contrary to law and fact, for it was published before the filing date of Scripps' '509 patent application and Scripps did not attempt to antedate the Meyer paper. It is thus immaterial when the Meyer abstract was published.

[12] Genentech also charged Scripps with inequitable conduct because Scripps originally sought claims to its monoclonal antibodies to Factor VIII:RP, and cancelled these claims after the examiner required Scripps to provide comparative data with the monoclonal antibodies described in the Meyer abstract and other references. While Genentech argues that obtaining such data was not the burden that Scripps said it was, this is irrelevant to the issue of inequitable conduct. An applicant has the absolute right to decline to do work suggested by the PTO, and to withdraw claims that had been presented for examination, without incurring liability for inequitable conduct.

The district court reviewed the Meyer abstract's content and found, without challenge on this appeal, that:

[T]he Meyer et al. abstract contains no disclosure of the purification of Factor VIII:C. The Meyer et al. abstract contains no disclosure indicating that any of the monoclonal antibodies could be bound to substrate particles to form an immunoa[d]sorbent for isolation and

purification of VIII:C from the VIII:C/VIII:RP complex.

The court concluded:

Lacking such disclosure, the Meyer et al. abstract does not appear material to the examination of the claims that were presented in applicants' original application and issued in Patent No. 4,361,509.

Scripps, 666 F.Supp. at 1398, 3 USPQ2d at 1495. No error is ascribed to this conclusion. A reference that is material only to withdrawn claims can not be the basis of a holding of inequitable conduct. *Kimberly-Clark Corp. v. Johnson & Johnson Co.*, 745 F.2d 1437, 1457, 223 USPQ 603, 616-17 (Fed.Cir.1984).

The party with the burden of proof of inequitable conduct must meet the clear and convincing standard. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1417 n. 11, 5 USPQ2d 1112, 1117 n. 11 (Fed.Cir.1987). Genentech did not offer evidence or legal argument whereby, even drawing all factual inferences in its favor, this standard could be met at trial, as to either materiality of the Meyer abstract, or intent to deceive or mislead. The district court's grant of partial summary judgment of no inequitable conduct based on the Meyer abstract is affirmed.

VIII

Infringement of the Product-by-Process Claims

Scripps appeals the district court's refusal to grant its motion for summary judgment of infringement of the R'011 product-by-process claims 13, 14, 17, 18, and 34. The district court denied Scripps' motion under Rule 59(e) to amend the judgment to rule on this question. Genentech argues that this denial is not appealable, and has moved for dismissal. Looking to the law of the Ninth Circuit, an appeal from a final judgment may include

challenges to "all rulings which produced the judgment". *Munoz v. Small Business Administration*, 644 F.2d 1361, 1364 (9th Cir.1981). See *Moran v. Aetna Life Insurance Co.*, 872 F.2d 296, 301 (9th Cir.1989) (denial of a summary judgment motion is appealable after entry of final judgment); 10 C. Wright, A. Miller, and M. Kane, *Federal Practice & Procedure* § 2715 (2d ed.1983). The issue is reviewable, but on an undeveloped record we consider only the questions of law.

[13] Scripps charges that Genentech's recombinantly-produced Factor VIII:C infringes the product-by-process claims, either literally or by application of the doctrine of equivalents. The district court remarked that the product-by-process claims would not be infringed unless the same process were practiced. Scripps correctly points out that this statement appears to diverge from our precedent, recognizing that this precedent arose in the context of patent prosecution, not patent infringement. *E.g., In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed.Cir.1985) (holding that prior art pertinent only to product is proper ground for rejecting product-by-process claims); *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972) (in product-by-process claims the patentability of the product must be established independent of the process); *In re Bridgeford*, 357 F.2d 679, 682 n. 5, 149 USPQ 55, 58 n. 5 (CCPA 1966) (recognizing that some courts in infringement litigation have construed product-by-process claims as limited to the particular process, but holding that patentability is determined independent of the process). In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims. Thus, these claims are subject to an infringement analysis similar to that

described in Part V, *ante*. Infringement of the product-by-process claims may be considered at trial.

IX

Attorney Fees

The district court held that this was an exceptional case under 35 U.S.C. § 285, apparently due to the court's rulings on inequitable conduct and failure to comply with the best mode. Holdings under § 285 are reviewed for abuse of the trial court's discretionary authority, considering the court's findings and conclusions and any other appropriate factors. See *Reactive Metals & Alloys Corp. v. ESM, Inc.*, 769 F.2d 1578, 1583, 226 USPQ 821, 824 (Fed.Cir.1985). In view of our reversal of the grants of summary judgment on the issues of best mode and inequitable conduct, the award of attorney fees flowing therefrom must be vacated. See *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1238, 224 USPQ 418, 426 (Fed.Cir.1985) (reversing ground for holding case exceptional and accompanying award of attorney fees).

X

Other Issues

We have not repeated all the arguments and issues raised by both sides, including charges of frivolity, misstatement, and worse. Encumbered by the summary nature of the proceedings, neither scientific nor evidentiary truth has risen easily to the surface. However, we *DENY* Scripps' motion for sanctions against Genentech for filing a frivolous cross-appeal, for some of the issues raised were not clearly hopeless in law and fact. We also *DENY* each side's motions to strike various materials filed and to dismiss issues raised by the other.

Costs

Each party shall bear its costs.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED.

FN* Circuit Judge Markey vacated the position of Chief Judge on June 27, 1990.

FN<<dagger>> The Honorable Peter Beer, United States District Court for the Eastern District of Louisiana, sitting by designation.

FN1. The plaintiffs will be grouped as "Scripps" unless otherwise stated. The defendants will be grouped as "Genentech" unless otherwise stated.

FN2. These consolidated appeals and cross-appeals arise from judgments and orders of the United States District Court for the Northern District of California. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 666 F.Supp. 1379, 3 USPQ2d 1481 (N.D.Cal.1987); *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 678 F.Supp. 1429, 6 USPQ2d 1018 (N.D.Cal.1988) (on reconsideration); *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 707 F.Supp. 1547, 11 USPQ2d 1187 (N.D.Cal.1989); and *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 724 F.Supp. 690, 12 USPQ2d 1157 (N.D.Cal.1989) (Order).

FN3. Drs. Zimmerman and Fulcher characterized the Factor VIII:C using a technique described as SDS-gel ("SDS" stands for sodium dodecyl sulfate) electrophoresis and production of a precipitating heterologous antibody. This work was reported in Fulcher and Zimmerman, *Proc. Nat'l Acad. Sci. USA*, "Characterization of the Human Factor VIII Procoagulant Protein with a Heterologous Precipitating Antibody", Vol. 79, pp. 1648-52, March, 1982. It is not disputed that this is the first time that human Factor VIII:C was sufficiently pure to be characterized scientifically, and that the Zimmerman/Fulcher characterization is now the generally recognized "fingerprint" of Factor VIII:C.

FN4. "Potency" refers to the amount of activity in a given volume of solution. For example, if 1000 units of Factor VIII:C activity were dissolved in 1 milliliter (ml) of water, the potency of the solution would be 1000 units/ml.

"Specific activity" refers to the number of units of activity for a given mass of protein. For example, if 1000 units of Factor VIII:C activity were present in 1/2 milligram (mg) of protein, the specific activity would be 2,000 units/mg.

One "Unit" is defined as the activity present in 1 ml of normal plasma.

FN5. "Fold purification" is the ratio of the specific activity of a protein sample to the specific activity of normal plasma. The Factor VIII:C specific activity of normal human plasma is known to be 0.014 units/mg. Thus the relationship is:

$$\text{fold purification} = \frac{\text{specific activity}}{0.014}$$

For example, if a Factor VIII:C sample has a specific activity of 2240 units/mg, its fold purification value is 160,000. Stated another way, the sample is 160,000 times purer, as to Factor VIII:C, than normal plasma.

FN6. The several defendants herein all presented arguments to the examiner, in Protests filed during the reissue proceeding, on why the product claims should not be allowed.

FN7. Broadened claims by reissue must be applied for within two years of grant of the original patent. 35 U.S.C. § 251. This requirement was met.

FN8. The patent examiner and the PTO Office of Quality Review found that the applicant adhered to correct reissue practice, pursuant to Manual of Patent Examining Procedure § 1456 (Rev. 3, 1986).

FN9. In accordance with the recombinant procedure, the human Factor VIII:C gene is identified, isolated, and inserted into a host cell, where it is replicated and from which Factor VIII:C is expressed and excreted into a culture medium. From this medium it is further purified using, *inter alia*, monoclonal antibodies to Factor VIII:C.

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(Cite as: 18 U.S.P.Q.2d 1001, *1015)

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United States Court of Customs and Patent
Appeals.

In re Georges JOLLES.

Appeal No. 80-510.

July 31, 1980.

Appeal was taken from decision of Patent and Trademark Office Board of Appeals which affirmed an examiner's rejection of claims 7-14, 16, 27-34 and 36 of Serial No. 652,848 encompassing certain pharmaceutical compositions and methods useful for treatment of acute myeloblastic leukemia in human patients. The United States Court of Customs and Patent Appeals, Baldwin, J., held that affidavit indicating that one of the pharmaceutical compounds has been effective in bringing out remission of a particular type of leukemia in 53 out of 100 patients, along with evidence of efficacy of the compounds when tested on laboratory animals, was sufficient to show that closely related compounds, which were structurally related to known chemotherapy drugs, had the requisite utility.

Reversed.

West Headnotes

[1] Patents ⇨ 49

291k49 Most Cited Cases

Proof of utility is sufficient if it is convincing to one of ordinary skill in the art.

[2] Patents ⇨ 49

291k49 Most Cited Cases

Affidavit indicating that one of the pharmaceutical compounds has been effective in bringing out remission of a particular type of leukemia in 53 out of 100 patients, along with evidence of efficacy of the compounds when tested on laboratory animals, was sufficient to show that closely related compounds, which were structurally related to

known chemotherapy drugs, had the requisite utility for treatment of acute myeloblastic leukemia in human patients.

Patents ⇨ 328(2)

291k328(2) Most Cited Cases

3,590,028, 3,686,163, 3,957,755, 3,965,088.
Cited.

*1322 Ellsworth H. Mosher, Arlington, Va., attorney of record for appellant; Charles A. Wendel, Harold C. Wegner, Arlington, Va., of counsel.

Joseph F. Nakamura, Washington, D. C., for the Commissioner of Patents and Trademarks; Gerald H. Bjorge, Washington, D. C., of counsel.

Before MARKEY, Chief Judge, RICH, BALDWIN and MILLER, Judges, and FORD, Judge. [FN*]

FN* The Honorable Morgan Ford, United States Customs Court, sitting by designation.

BALDWIN, Judge.

This appeal is from the decision of the Patent and Trademark Office Board of Appeals (board) affirming the examiner's rejection of claims 7-14, 16, 27-34 and 36 [FN1] under 35 U.S.C. s 101 [FN2] and 35 U.S.C. s 112, first paragraph, [FN3] for lack of proof of utility. We reverse.

FN1. The claims appear in application Serial No. 652,848 (subject application), filed January 27, 1976, and entitled "Naphthacene Derivatives." The application is a division of Serial No. 307,955, filed November 20, 1972, now Patent No. 3,965,088, which in turn is a continuation-in-part of Serial No. 187,559, filed October 7, 1971, now Patent No. 3,957,755, which in turn is a continuation-in-part of Serial No. 768,532, filed October 17, 1968, now abandoned.

FN2. 35 U.S.C. s 101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of

matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

FN3. 35 U.S.C. s 112, first paragraph, provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

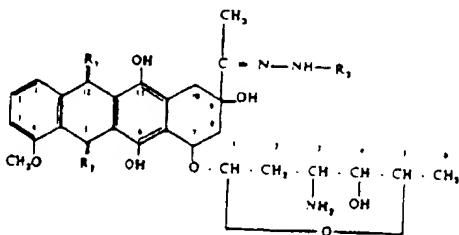
Background

Composition claims 7-14 and 16 encompass certain pharmaceutical compositions *1323 useful for the treatment of acute myeloblastic leukemia which comprise certain naphthacene derivatives. Method claims 27-34 and 36 encompass methods for the treatment of acute myeloblastic leukemia in a human patient by administering the subject naphthacene derivatives. Claims to the derivatives per se have been allowed in Patents No. 3,965,088 and 3,957,755.[FN4]

FN4. See n.1 supra.

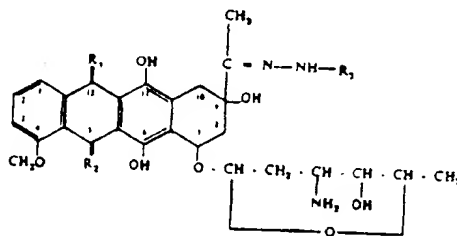
The invention is represented by generic claims 7 and 28, reproduced below. As stated explicitly in the method claims, and as recognized by appellant in his brief, the compositions are intended for use in the treatment of acute myeloblastic leukemia in human patients.

7. A pharmaceutical composition for parenteral administration and useful for the treatment of acute myeloblastic leukaemia which comprises, as active ingredient, a naphthacene of the formula:



wherein one of R 1 and R 2 is oxygen and the other is oxygen or = N - NHR 3, and R 3 is alkanoyl of up to 4 carbon atoms, alkanoyl of up to 4 carbon atoms substituted by a sulphonic acid group, alkanoyl of up to 4 carbon atoms substituted by a quaternary ammonium group, thiocarbamoyl, methylthiocarbamoyl, amidino, or benzoyl, or a non-toxic salt thereof, in association with a significant amount of a sterile injectable pharmaceutically-acceptable carrier.

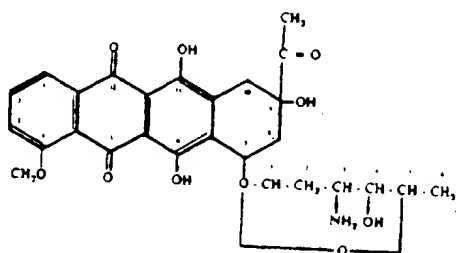
28. Method for the treatment of acute myeloblastic leukaemia in a human patient which comprises administering parenterally to the patient a quantity of from 2 to 10 mg/kg per day of a naphthacene of the formula:



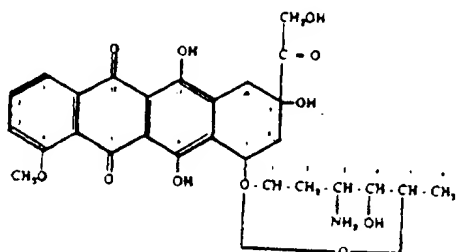
wherein one of R 1 and R 2 is oxygen and the other is oxygen or = N - NHR 3, and R 3 is alkanoyl of up to 4 carbon atoms, alkanoyl of up to 4 carbon atoms substituted by a sulphonic acid group, alkanoyl of up to 4 carbon atoms substituted by a quaternary ammonium group, thiocarbamoyl, amidino, or benzoyl, or a non-toxic salt thereof.

The derivatives bear a close structural relationship to daunorubicin [FN5] and doxorubicin,[FN6] both of which are well recognized in the art as valuable for use in cancer chemotherapy.[FN7]

FN5. Daunorubicin:



FN6. Doxorubicin, also referred to as adriamycin, U.S. Patent No.



FN7. The Merck index refers to each of these as "antineoplastic," i. e., antagonistic with respect to the formation of new growths.

Affidavit Evidence Jacquillat Declarations

Two declarations by Dr. Claude Jacquillat were submitted in application Serial No. *1324 187,559, and were before the examiner and the board in the prosecution of the subject application. Both declarations report results of clinical treatment of human patients suffering from acute myeloblastic leukemia with one of the claimed compositions.[FN8] The second declaration dated January 3, 1974, reports results of treatment of 100 patients under the personal supervision of Dr. Jacquillat and the method of diagnosis of acute myeloblastic leukemia, and includes the results of the treatment of 33 patients reported in the first declaration dated August 28, 1972. Dr. Jacquillat outlined the dosage rate, the length of dosage, and methods of evaluating its effect through daily blood counts and periodic bone marrow examination. Among the results reported, complete remission of the disease was achieved in 53 of

the patients treated. Dr. Jacquillat concluded that the specific composition used is an active drug in the treatment of acute myeloblastic leukemia and is a valuable addition to the series of drugs available for such treatment.

FN8. Claims 15 and 35, which stand allowed, are directed to the specific pharmaceutical composition and corresponding method for treatment reported by Dr. Jacquillat in his declarations. Claim 15 reads:

15. A composition according to Claim 7 in which active ingredient is 4- methoxy-5,12-dioxo-6,9,11-trihydroxy-7-(2,3,3-O-tridesoxy-3-amino-1-L-lyxohexosyl)-9-(1-(benzoylhydrazono)ethyl)-5, 7, 8, 9, 10, 12- hexahydronaphthacene, or a non-toxic acid addition salt thereof.

Maral Declarations

Two declarations by Dr. Rene Maral were before the examiner and the board in the prosecution of the subject application. The first declaration, dated January 22, 1971, in application Serial No. 768,532, disclosed results of experimental tests with laboratory mice wherein tests for sub-acute toxicity, activity against sarcoma 180 tumors, and activity against leukemia L 1210 of seven specific compositions were reported. The compositions tested were those described in examples 1-7 of the subject application. The seventh composition was the same composition utilized in the Jacquillat clinical tests. See n.8 supra. On the basis of reported results, Dr. Maral concluded that "the compounds of * * * Application Serial No. 768,532 have substantial activity against experimental tumours in mice in tests customarily used for the screening of anti-cancer agents of potential utility in the treatment of humans."

The second declaration, dated January 31, 1975, in application Serial No. 307,955, disclosed similar results from the same tests for sub-acute toxicity and anti-tumor activity for an additional composition corresponding to that described in example 8 of the subject application. On the basis of reported results, Dr. Maral concluded that the specific composition tested "has a substantial activity against experimental tumours in mice in tests customarily used for the screening of anti-

cancer agents of potential utility in the treatment of humans."

The eight compounds tested by Dr. Maral are structurally related, the differences residing in the second C 9 substituent, being other than a hydroxy group. See claims 7 and 28 supra. Appellant provided the following tabulation of differences for the eight compounds tested.

| Species Composition Claim | Species Method Claim | The Second C, Substituent |
|---------------------------------|----------------------------|--|
| 9 | 29 | 1- (3-sulphopropionyl-hydrazono) ethyl |
| 10 | 30 | 1- (trimethyl-ammonio- acetylhydrazono) ethyl |
| 11 * | 31 * | 1- (thiosemicarbazono) ethyl |
| 12 | 32 | 1- (amidino-hydrazono) ethyl |
| 13 * | 33 * | 1- (thiosemicarbazono) ethyl |
| 14 | 34 | 1- (4-methylthiosemicarbazono) ethyl |
| 15 | 35 | 1- (benzoylhydrazono) -ethyl |
| 16 | 36 | 1- (formylhydrazono) ethyl |

FN* Here the second C, substituent is the same, but the claims differ slightly in the naphthacene nucleus in that in the active ingredient recited in the latter pair of claims only one oxo (O) need be present at the C sub5 and C sub12 positions.

The Rejection

The examiner, relying on no prior art, rejected claims 7-16 and 27-36 under 35 U.S.C. s 101 and 35 U.S.C. s 112, first paragraph, "for lack of proof of utility." *1325 The examiner, in her answer, found there was "insufficient evidence of operativeness in the record that the various compositions are safe and effective to treat acute myeloblastic leukaemia in human patients," citing In re Citron, 51 CCPA 852, 325 F.2d 248, 139 USPQ 516 (1963), for support. The examiner further asserted:

The instant claims are directed to an

incredible utility. The method of treating a human leukaemia and a pharmaceutical composition for this use employing appellant's naphthacene compounds have not been set forth in the specification as required by the statute. There are no specific examples or test data showing the effectiveness of the claimed pharmaceutical compositions for the alleged use which would include a specific dosage for a specific patient and duration of treatment. The dosage range given for the active ingredient, i. e. the naphthacene compound in the composition is 2-10 mg./kg. per day. It is not stated in the specification, however, whether the dosage

should be given periodically or in a single dose, nor what a total dosage should be. Accordingly, appellant has not made known exactly how his invention is to be used, but rather, has left the matter of how to use to speculation. * * *

The Declaration of Dr. Jacquillat * * * has again been carefully considered, but is not convincing. The Declaration shows the use of only one of the compounds used in appellant's invention, which is the pharmaceutical composition of claim 15 and the method of claim 35. This compound is referred to as product "g" in the Declaration which shows that out of 100 patients treated with product "g", only 53 (53%) had complete remission after 30 to 40 days of treatment * * *. The remission was not of long duration as shown in Table II of the Declaration. Table I of the Declaration shows that death occurred in thirteen adults during induction of the treatment. Therefore, this data is not deemed persuasive that product "g", the compound used in claims 15 and 35, is safe and effective for treating acute myeloblastic leukaemia in humans.

With regard to the various other naphthacene compounds employed in appellant's methods and compositions of claims 7-14, 16-34 and 36, due to the unpredictability of chemical compounds and side reactions, and therapeutic conditions such as leukaemia, it would not be reasonable for a person of ordinary skill in the art to presume that these novel compounds would be safe and effective for the incredible utility alleged in the absence of verified data substantiating the said allegations of use.

The Board

The board sustained the rejection of claims 7-14, 16, 27-34 and 36 but not the rejection of claims 15 and 35. The board reasoned as follows:

We have carefully considered all of the arguments and evidence and conclude that the results set forth in the Maral declaration exhibit effectiveness for each of the claimed compositions with respect to the treatment of experimental tumors, i. e., sarcoma 180 and leukemia L1210 in mice and hence establish

the utility of the compositions in mice. * * * We think it is clear from appellant's remarks that the present claims on appeal contemplate only human utility. In that regard, the Maral evidence is not relevant. With respect to the additional evidence set forth in the declarations of Professor Jacquillat regarding the treatment of humans afflicted with acute myeloblastic leukemia, we find that only one compound was tested relating to the operativeness of the claimed subject matter. In carefully evaluating the Jacquillat evidence, we observe that the active ingredient of claims 15 and 35 administered in the manner taught in the specification is useful to some degree inasmuch as remissions in 53% of the patients were achieved and we therefore conclude that the operativeness of said compound is sufficiently established to satisfy the requirements of 35 U.S.C. s 101 and the first paragraph of *1326 35 U.S.C. s 112. With respect to the Examiner's contention that it has not been demonstrated that the claimed invention is safe, we refer to *In re Anthony*, 56 CCPA 1443, 414 F.2d 1383, 162 USPQ 594 (1969) and *In re Watson*, 517 F.2d 465, 186 USPQ 11 ((Cust. and Pat. App.) 1975) which hold that claims may satisfy the requirements of 35 U.S.C. s 101 for utility despite the lack of safety. * * *

The Jacquillat evidence, however, which is limited to one compound is insufficient to satisfy the requirements of 35 U.S.C. s 101 with respect to the remaining claims in view of the nature of the utility and the scope of the claims. There is no indication that the compounds of claims 7 to 14, 16, 27 to 34 and 36 which differ in structure from the benzoyl-hydrazono compound of claims 15 and 35 are effective in the treatment of acute myeloblastic leukemia.

Appellant appears to rely upon the analogy with the known compounds "daunorubicin and doxorubicin" to provide the utility requirements for all of the compositions. The claimed products differ from the aforesaid prior art compounds in the replacement of keto groups at C-9 and/or at one of C-5 and C-12 positions with an = N-NH-R 3 grouping, wherein R 3 is set forth as a variety of substituents. We note that the Examiner has

reviewed the prior art as represented by the Arcamone et al. patents ([FN9]) and determined that the claimed compositions were not prima facie obvious therefrom. We cannot conclude that the claimed compositions are so similar to those of the prior art as to expectedly have the same specific utility of treating acute myeloblastic leukemia in humans. On the record before us, considering the nature of the stated utility, we cannot conclude that appellant has submitted sufficient evidence of demonstrated utility commensurate with the scope of the claims. We find the quantum of evidence represented by a single compound falls far short in proving the asserted utility.

FN9. The Arcamone et al. patents, U.S. Patents No. 3,590,028 and 3,686,163, were cited as prior art references in the prosecution of U.S. Patents No. 3,957,755 and 3,965,088, wherein claims for the naphthacene derivative compositions per se were allowed. See n.1 supra.

OPINION

While the rejection below was under both 35 U.S.C. s 101 and 35 U.S.C. s 112, first paragraph, the dispositive issue is whether appellant has submitted sufficient evidence to establish his asserted utility of the compositions and methods of the rejected claims for the treatment of acute myeloblastic leukemia in human patients.[FN10] The examiner in her rejection raised questions on the legal adequacy of appellant's disclosure of how to use the claimed compounds under 35 U.S.C. s 112, first paragraph, viz., the specific dosage and duration of treatment, but the board has specifically rejected this argument with regard to claims 15 and 35, and the solicitor does not argue this further in his brief. Accordingly, we consider the rejection under both provisions to turn on the proof of utility issue.

FN10. Absence of asserted utility may lead to a rejection under either 35 U.S.C. s 101 or 35 U.S.C. s 112. In re Gardner, 475 F.2d 1389, 1392, 177 USPQ 396, 398 (Cust. and Pat.App.1973).

The contents of the declarations in the record

and the qualifications of the declarants have not been challenged, so we accept their contents and conclusions at face value.

[1] Proof of utility is sufficient if it is convincing to one of ordinary skill in the art. In re Irons, 52 CCPA 938, 340 F.2d 974, 144 USPQ 351 (1965). The amount of evidence required depends on the facts of each individual case. In re Gazave, 54 CCPA 1524, 379 F.2d 973, 154 USPQ 92 (1967). The character and amount of evidence needed may vary, depending on whether the alleged utility appears to accord with or to contravene established scientific principles and beliefs. In re Chilowsky, 43 CCPA 775, 229 F.2d 457, 108 USPQ 321 (1956).

***1327** [2] The examiner in her rejection referred to the "incredible utility" of the subject claims. The solicitor in his brief further argues that "(a)t best the asserted usefulness here is highly speculative and against the grain of human experience. At worst it is incredible." Neither the solicitor nor the examiner provides support for the assertion regarding "incredible utility." Such assertions have been readily rebutted by the Jacquillat evidence together with the known utility of daunorubicin and doxorubicin, which clearly establish that the medical treatment of a specific cancer is not such an inherently unbelievable undertaking or involves such implausible scientific principles as to be considered incredible.

The board avoided the examiner's assertion of incredible utility, but did question the operativeness of the claimed subject matter. When utility as a drug, medicant, and the like in human therapy is alleged, it is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct. In re Novak, 49 CCPA 1283, 306 F.2d 924, 134 USPQ 335 (1962).

However, in considering the evidence proffered by appellant, the board dismissed the Maral declarations as not relevant to establish the claimed human utility. The Jacquillat clinical tests were accepted by the

(Cite as: 628 F.2d 1322, *1327)

board solely for the establishment of utility for the specific composition tested.

We believe the board erred in dismissing the Maral evidence as not relevant to human utility. This court recognizes "that a demonstration that a compound has desirable or beneficial properties in the prevention, alleviation, or cure of some disease or manifestation of a disease in experimental animals does not necessarily mean that the compound will have the same properties when used with humans." *In re Krimmel*, 48 CCPA 1116, 1123, 292 F.2d 948, 953, 130 USPQ 215, 219 (1961). However, this is by no means support for the board's position that such evidence is not relevant to human utility.

To the contrary, this court has accepted tests on experimental animals as sufficient to establish utility in *In re Bergel*, 48 CCPA 1102, 292 F.2d 955, 130 USPQ 206 (1961). Utility was recognized by this court in *Bergel* not because of any concern with the health or existence of the experimental animals, but rather because of the widespread pharmacological work in animals recognized as a screening procedure for testing new drugs. It is clear that such testing is relevant to utility in humans. Evidence showing substantial activity against experimental tumors in mice in tests customarily used for the screening of anti-cancer agents of potential utility in the treatment of humans is relevant to utility in humans and is not to be disregarded. *In re Buting*, 57 CCPA 777, 418 F.2d 540, 163 USPQ 689 (1969).

The board, after evaluating the Jacquillat evidence, concluded that the operativeness of the specific derivative utilized in the Jacquillat clinical tests was sufficiently established to satisfy the utility requirements of sections 101 and 112, first paragraph, and accordingly did not sustain the examiner's rejection of claims 15 and 35. However, the board found the quantum of evidence represented by the single derivative to fall far short in proving the asserted utility for the remaining claimed derivatives. The board erred in this finding by failing to give sufficient weight to the similarity of the

remaining claimed derivatives to the derivative in allowed claims 15 and 35 when considered with the Maral animal tests.

The similarities of the claimed derivatives to each other are represented in the tabulation of differences provided supra for the eight compounds tested by Dr. Maral. The Maral declarations establish that the eight compounds have substantial activity against experimental tumors in mice. The board found that the successful clinical tests in humans of the one derivative shown in the Jacquillat declarations sufficiently established utility for claims 15 and 35. The claimed compounds have a close structural relationship to daunorubicin and doxorubicin, both known to be useful in cancer chemotherapy. Considering these facts in the record before us, we conclude that one *1328 of ordinary skill in the art would accept appellant's claimed utility in humans as valid and correct. The decision of the board is reversed.

REVERSED.

628 F.2d 1322, 206 U.S.P.Q. 885

END OF DOCUMENT

Briefs and Other Related Documents

United States Court of Appeals,
Federal Circuit.

**VERDEGAAL BROTHERS, INC., William
Verdegaal, George Verdegaal, Appellees,**
v.

**UNION OIL COMPANY OF
CALIFORNIA, Brea Agricultural
Services, Inc., Appellants.**

Appeal No. 86-1258.

March 12, 1987.

Action was instituted for alleged patent infringement. The United States District Court for the Eastern District of California, Robert E. Coyle, J., entered judgment on verdict for plaintiff, declaring patent valid and infringed, and defendants appealed. The Court of Appeals, Nies, Circuit Judge, held that patent relating to a process for making urea-sulfuric acid liquid fertilizer by reacting water, urea, a nitrogen-containing chemical, and sulfuric acid, a sulfur-containing chemical, in particular proportions was anticipated by prior art reference disclosing processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers and was invalid.

Reversed.

See also, Fed.Cir., 750 F.2d 947.

West Headnotes

[1] Federal Civil Procedure ⇨ 2609
170Ak2609 Most Cited Cases

A district court presented with a motion for judgment notwithstanding the verdict should consider all of the evidence, in a light most favorable to nonmoving party, drawing all reasonable inferences favorable to that party, without determining credibility of witnesses, and without substituting its choice for that of the jury and deciding between conflicting elements of the evidence, and should grant the

motion only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. 35 U.S.C.A. §§ 102, 103; Fed.Rules Civ.Proc.Rule 50(a, b), 28 U.S.C.A.

[2] Federal Civil Procedure ⇨ 2608.1
170Ak2608.1 Most Cited Cases
(Formerly 170Ak2608)

Party moving for judgment notwithstanding the verdict must show that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury and forming its verdict. 35 U.S.C.A. §§ 102, 103; Fed.Rules Civ.Proc.Rule 50(a, b), 28 U.S.C.A.

[3] Patents ⇨ 36(2)
291k36(2) Most Cited Cases

Presumption of validity afforded a patent requires that party challenging validity prove facts establishing invalidity by clear and convincing evidence. 35 U.S.C.A. § 282.

[4] Patents ⇨ 72(1)
291k72(1) Most Cited Cases

A claim is anticipated only if each and every element as set forth in claim is found, either expressly or inherently described, in a single prior art reference. 35 U.S.C.A. § 102(e).

[5] Patents ⇨ 66(1.12)
291k66(1.12) Most Cited Cases
Preparations.

Patent relating to a process for making urea-sulfuric acid liquid fertilizer by reacting water, urea, a nitrogen-containing chemical, and sulfuric acid, a sulfur-containing chemical, in particular proportions was anticipated by prior art reference disclosing processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers and was invalid. 35 U.S.C.A. §§ 102(e), 282.

[6] Patents ⇨ 72(1)

291k72(1) Most Cited Cases

It was inappropriate for holder of patented fertilizer process to rely on fact that sulfuric acid was added slowly in prior art reference, whereas claimed process allowed for rapid addition, where there was no limitation in subject process with respect to rate at which sulfuric acid was added. 35 U.S.C.A. §§ 102(e), 282.

[7] Patents ⇌ 62(1)

291k62(1) Most Cited Cases

Discarding testimony of experts with respect to what prior art reference taught did not eliminate reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process could be used to make more of the product and, hence, did not preclude conclusion that claimed process for making liquid fertilizer was invalid as anticipated by prior art. 35 U.S.C.A. §§ 102(e), 282.

[8] Patents ⇌ 72(1)

291k72(1) Most Cited Cases

Failure of prior art reference to explicitly identify heel in process for manufacturing liquid fertilizer as a heat sink did not preclude reference from anticipating claimed process, thus requiring a finding of invalidity, where fact that heel functioned as a heat sink was inherent in prior art reference. 35 U.S.C.A. §§ 102(e), 282.

Patents ⇌ 328(2)

291k328(2) Most Cited Cases

4,310,343. Declared invalid as anticipated by prior art.

Patents ⇌ 328(2)

291k328(2) Most Cited Cases

4,315,763. Prior art.

*629 Andrew J. Belansky, Christie, Parker & Hale, Pasadena, Cal., argued for appellants.

*630 With him on the brief was David A. Dillard.

John P. Sutton, Limbach, Limbach & Sutton, San Francisco, Cal., argued for appellees. With him on the brief was Michael E. Dergosits.

Before MARKEY, Chief Judge, and DAVIS and NIES, Circuit Judges.

NIES, Circuit Judge.

Union Oil Company of California and Brea Agricultural Services, Inc. (collectively Union Oil) appeal from a judgment of the United States District Court for the Eastern District of California, No. CV-F-83-68 REC, entered on a jury verdict which declared U.S. Patent No. 4,310,343 ('343), owned by Verdegaal Brothers, Inc., "valid" and claims 1, 2, and 4 thereof infringed by Union Oil. Union Oil's motion for judgment notwithstanding the verdict (JNOV) was denied. We reverse.

I

BACKGROUND

The General Technology

The patent in suit relates to a process for making certain known urea-sulfuric acid liquid fertilizer products. These products are made by reacting water, urea (a nitrogen-containing chemical), and sulfuric acid (a sulfur-containing chemical) in particular proportions. The nomenclature commonly used by the fertilizer industry refers to these fertilizer products numerically according to the percentages by weight of four fertilizer constituents in the following order: nitrogen, phosphorous, potassium, and sulfur. Thus, for example, a fertilizer containing 28% nitrogen, no phosphorous or potassium, and 9% sulfur is expressed numerically as 28-0-0-9.

The Process of the '343 Patent

The process disclosed in the '343 patent involves the chemical reaction between urea and sulfuric acid, which is referred to as an exothermic reaction because it gives off heat. To prevent high temperature buildup, the reaction is conducted in the presence of a nonreactive, nutritive heat sink which will absorb the heat of reaction. Specifically, a

previously-made batch of liquid fertilizer--known as a "heel"--can serve as the heat sink to which more reactants are added. Claims 1 and 2 are representative:

1. In a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product, the improvement comprising:
 - a. providing a non-reactive, nutritive heat sink, capable of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product,
 - b. adding water to the heat sink in an amount not greater than 15% of the end product,
 - c. adding urea to the mixture in an amount of at least 50% of the total weight of the end product,
 - d. adding concentrated sulfuric acid in an amount equal to at least 10% of the total weight of the end product.
2. The process of claim 1 wherein the heat sink is recycled liquid fertilizer.

Procedural History

Verdegaal brought suit against Union Oil in the United States District Court for the Eastern District of California charging that certain processes employed by Union Oil for making liquid fertilizer products infringed all claims of its '343 patent. Union Oil defended on the grounds of noninfringement and patent invalidity under 35 U.S.C. §§ 102, 103. The action was tried before a jury which returned a verdict consisting of answers to five questions. Pertinent here are its answers that the '343 patent was "valid" over the prior art, and that certain of Union Oil's processes infringed claims 1, 2, and 4 of the patent. None were found to infringe claims 3 or 5. Based on the jury's verdict, the district court entered judgment in favor of Verdegaal.

Having unsuccessfully moved for a directed verdict under Fed.R.Civ.P. 50(a), Union Oil timely filed a motion under Rule 50(b) for JNOV seeking a judgment that the claims of the '343 patent were invalid *631 under sections 102 and 103. The district court denied the motion without opinion.

II ISSUE PRESENTED

Did the district court err in denying Union Oil's motion for JNOV with respect to the validity of claims 1, 2, and 4 of the '343 patent?

III Standard of Review

[1] When considering a motion for JNOV a district court must: (1) consider all of the evidence; (2) in a light most favorable to the non-moving party; (3) drawing all reasonable inferences favorable to that party; (4) without determining credibility of the witnesses; and (5) without substituting its choice for that of the jury's in deciding between conflicting elements of the evidence. *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512-13, 220 USPQ 929, 936 (Fed.Cir.), cert. denied, 469 U.S. 871, 105 S.Ct. 220, 83 L.Ed.2d 150 (1984); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1546, 220 USPQ 193, 197 (Fed.Cir.1983). A district court should grant a motion for JNOV only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. *Railroad Dynamics*, 727 F.2d at 1513, 220 USPQ at 936; *Connell*, 722 F.2d at 1546, 220 USPQ at 197.

[2] To reverse the district court's denial of the motion for JNOV, Union Oil must convince us that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury in forming its verdict. See *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed.Cir.), cert. denied, 469 U.S. 857, 105 S.Ct. 187, 83 L.Ed.2d 120 (1984); *Railroad Dynamics*, 727 F.2d at 1512, 220 USPQ at 936. Substantial evidence is more than just a mere scintilla; it is such relevant evidence from the record taken as a whole as a reasonable mind might accept as adequate to support the finding under review. *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229, 59 S.Ct. 206, 216, 83 L.Ed. 126 (1938); *Perkin-Elmer*, 732 F.2d at 893, 221

USPQ at 673; *SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n*, 718 F.2d 365, 371 n. 10, 218 USPQ 678, 684 n. 10 (Fed.Cir.1983). A trial court's denial of a motion for JNOV must stand unless the evidence is of such quality and weight that reasonable and fair-minded persons in the exercise of impartial judgment could not reasonably return the jury's verdict. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758, 221 USPQ 473, 477 (Fed.Cir.1984).

[3] Our precedent holds that the presumption of validity afforded a U.S. patent by 35 U.S.C. § 282 requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed.Cir.), cert. denied, 469 U.S. 821, 105 S.Ct. 95, 83 L.Ed.2d 41 (1984). Thus, the precise question to be resolved in this case is whether Union Oil's evidence is so clear and convincing that reasonable jurors could only conclude that the claims in issue were invalid. See *Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics*, 727 F.2d at 1511, 220 USPQ at 935.

Anticipation

[4] A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See, e.g., *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715, 223 USPQ 1264, 1270 (Fed.Cir.1984); *Connell*, 722 F.2d at 1548, 220 USPQ at 198; *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir.1983), cert. denied, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984). Union Oil asserts that the subject claims of the '343 patent *632 are anticipated under 35 U.S.C. § 102(e) [FN1] by the teachings found in the original application for U.S. Patent No. 4,315,763 to Stoller, which the jury was instructed was prior art.

FN1. Section 102(e) provides:

A person shall be entitled to a patent unless--

....

(e) the invention was described in a patent granted

on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent....

[5] From the jury's verdict of patent validity, we must presume that the jury concluded that Union Oil failed to prove by clear and convincing evidence that claims 1, 2, and 4 were anticipated by the Stoller patent. See *Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics*, 727 F.2d at 1516, 220 USPQ at 939. Under the instructions of this case, this conclusion could have been reached only if the jury found that the Stoller patent did not disclose each and every element of the claimed inventions. Having reviewed the evidence, we conclude that substantial evidence does not support the jury's verdict, and, therefore, Union Oil's motion for JNOV on the grounds that the claims were anticipated should have been granted.

The Stoller patent discloses processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers. Example 8 of Stoller specifically details a process for making 30-0-0-10 urea-sulfuric acid products. There is no dispute that Example 8 meets elements b, c, and d of claim 1, specifically the steps of adding water in an amount not greater than 15% of the product, urea in an amount of at least 50% of the product, and concentrated sulfuric acid in an amount of at least 10% of the product. Verdegaal disputes that Stoller teaches element a, the step of claim 1 of "providing a non-reactive, nutritive heat sink." As set forth in claim 2, the heat sink is recycled fertilizer. [FN2]

FN2. Claim 4 is written in terms of approximate percentages of all reactants by weight of the end product. No argument is made that the process of claim 4 would result in a fertilizer product any different from that disclosed by Example 8 of Stoller.

The Stoller specification, beginning at column 7, line 30, discloses:

Once a batch of liquid product has been

made, it can be used as a base for further manufacture. This is done by placing the liquid in a stirred vessel of appropriate size, adding urea in sufficient quantity to double the size of the finished batch, adding any water required for the formulation, and slowly adding the sulfuric acid while stirring. Leaving a heel of liquid in the vessel permits further manufacture to be conducted in a stirred fluid mass.

This portion of the Stoller specification explicitly teaches that urea and sulfuric acid can be added to recycled fertilizer, i.e., a heel or base of previously-made product. Dr. Young, Union Oil's expert, so testified. Verdegaal presented no evidence to the contrary.

[6] Verdegaal first argues that Stoller does not anticipate because in Stoller's method sulfuric acid is added *slowly*, whereas the claimed process allows for rapid addition. However, there is no limitation in the subject claims with respect to the rate at which sulfuric acid is added, and, therefore, it is inappropriate for Verdegaal to rely on that distinction. See *SSIH*, 718 F.2d at 378, 218 USPQ at 689. It must be assumed that slow addition would not change the claimed process in any respect including the function of the recycled material as a heat sink.

[7] Verdegaal next argues that the testimony of Union Oil's experts with respect to what Stoller teaches could well have been discounted by the jury for bias. Discarding that testimony does not eliminate the reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process may be used to make more of the product.

[8] Verdegaal raises several variations of an argument, all of which focus on the *633 failure of Stoller to explicitly identify the heel in his process as a "heat sink." In essence, Verdegaal maintains that because Stoller did not recognize the "inventive concept" that the heel functioned as a heat sink, Stoller's process cannot anticipate. This argument is wrong as a matter of fact and law. Verdegaal's own expert, Dr. Bahme, admitted

that Stoller discussed the problem of high temperature caused by the exothermic reaction, and that the heel could function as a heat sink. [FN3] In any event, Union Oil's burden of proof was limited to establishing that Stoller disclosed the same process. It did not have the additional burden of proving that Stoller recognized the heat sink capabilities of using a heel. Even assuming Stoller did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention. See *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971). The pertinent issues are whether Stoller discloses the process of adding urea and sulfuric acid to a previously-made batch of product, and whether that base would in fact act as a heat sink. On the entirety of the record, these issues could only be resolved in the affirmative.

FN3. There is no dispute that the percentage of heel described in Stoller meets the percentage of heat sink required by the claims.

On appeal Verdegaal improperly attempts to attack the status of the Stoller patent as prior art, stating in its brief:

Verdegaal also introduced evidence at trial that the Stoller patent is not prior art under 35 U.S.C. §§ 102(e)/103. Professor Chisum testified that the Stoller patent, in his opinion, was not prior art.... This conclusion finds support in *In re Wertheim*, 646 F.2d 527 (CCPA 1981), and 1 Chisum on Patents § 3.07[3].

Appellee Brief at 27 (record cite omitted). Seldom have we encountered such blatant distortion of the record. A question about the status of the Stoller disclosure as prior art did arise at trial. Union Oil asserted that, even though the Stoller patent issued after the '343 patent, Stoller was prior art under section 102(e) as of its filing date which was well before the filing date of Verdegaal's application. Professor Chisum never testified that the Stoller patent was *not* prior art, but rather, stated that *he did not know* whether it

was prior art. An excerpt from the pertinent testimony leaves no doubt on this point:

Q. (Mr. Sutton): And do you know whether the Stoller patent is prior art to the application of the Verdegaal patent?

A. (Prof. Chisum): I don't know that it is, no.

We find it even more incredible that Verdegaal would attempt to raise an issue with respect to the status of the Stoller patent given that the case was submitted to the jury with the instruction that the original Stoller patent application was prior art. [FN4] Verdegaal made no objection to that instruction below, and in its appeal briefs, the instruction is cavalierly ignored.

FN4. The jury instruction read:

Stoller filed two patent applications--an original application on October 30th, 1978, and a second on February 7th, 1980. Under the patent laws, the claims of the 343 patent are invalid if you find that the original application (Exhibit BL) anticipates the process claimed in the 343 patent.

In sum, Verdegaal is precluded from arguing that the Stoller patent should not be considered prior art. See Fed.R.Civ.P. 51; *Weinar v. Rollform Inc.*, 744 F.2d 797, 808, 223 USPQ 369, 375 (Fed.Cir.1984), cert. denied, 470 U.S. 1084, 105 S.Ct. 1844, 85 L.Ed.2d 143 (1985); *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 615, 222 USPQ 654, 662 (Fed.Cir.), cert. denied, 469 U.S. 1038, 105 S.Ct. 516, 83 L.Ed.2d 405 (1984). [FN5]

FN5. Union Oil also argues that Verdegaal's counsel misled the jury by its closing rebuttal argument:

[B]ut I think it's important to keep in mind that [Stoller] couldn't have been a prior patent because it issued a month after the Verdegaal patent had issued.

We disapprove of Verdegaal's tactic which would form the basis for a grant of a motion for a new trial but for our conclusion that outright reversal of the ruling on the motion for JNOV is in order.

***634** After considering the record taken as a whole, we are convinced that Union Oil established anticipation of claims 1, 2, and 4 by clear and convincing evidence and that no reasonable juror could find otherwise.

Consequently, the jury's verdict on validity is unsupported by substantial evidence and cannot stand. Thus, the district court's denial of Union Oil's motion for JNOV must be reversed.

Conclusion

Because the issues discussed above are dispositive of this case, we do not find it necessary to reach the other issues raised by Union Oil. [FN6] In accordance with this opinion, we reverse the portion of the judgment entered on the jury verdict upholding claims 1, 2, and 4 of the '343 patent as valid under section 102(e) and infringed.

FN6. It should not be inferred that all of these issues were properly before us. Union Oil appears to assume that on appeal it may dispute the resolution of any issue which is denominated an "issue of law" even though it was not raised in its motion for JNOV. This is incorrect. See *Railroad Dynamics*, 727 F.2d at 1511, 220 USPQ at 934.

REVERSED.

814 F.2d 628, 2 U.S.P.Q.2d 1051

Briefs and Other Related Documents (Back to top)

. 1986 WL 732841 (Appellate Brief) Reply Brief for Appellants (Sep. 08, 1986)

. 1986 WL 732840 (Appellate Brief) Brief for Appellees (Aug. 22, 1986)

. 1986 WL 732839 (Appellate Brief) Brief for Appellants (Jul. 14, 1986)

END OF DOCUMENT

United States Court of Appeals,
Federal Circuit.

**Donald G. RICHARDSON, Plaintiff/
Appellant,**

v.

**SUZUKI MOTOR CO., LTD. and U.S.
Suzuki Motor Corporation, Defendants/
Cross-**

Appellants,

**Kawasaki Heavy Indust. Ltd., Kawasaki
Motors Corp., Yamaha Motor Co., Ltd.,
Yamaha Motor Corp., U.S.A., Kayaba
Industry Co., Ltd. and Kayaba Industry
Co.,
Defendants.**

**Nos. 87-1497, 87-1498, 87-1502, 88-1083 and
88-1084.**

Feb. 16, 1989.

Rehearing Denied March 29, 1989.

**Suggestion for Rehearing In Banc Declined
May 4, 1989.**

Appeals were taken from order of the United States District Court for the Central District of California, William P. Gray, J., entered following jury verdict in action for patent infringement, breach of contract, fraud, and misappropriation of trade secrets. The Court of Appeals, Pauline Newman, Circuit Judge, held that: (1) evidence sustained finding of validity; (2) evidence sustained finding of infringement; (3) evidence sustained finding of fraud; (4) evidence sustained finding of misappropriation of trade secrets; but (5) court's instruction on damages was improper.

Affirmed in part, reversed in part, vacated in part, and remanded.

West Headnotes

[1] Patents ⇨ 314(5)

291k314(5) Most Cited Cases

Jury may decide the questions of anticipation and obviousness, either as separate special verdicts or en route to a verdict on the

question of validity, which may also be decided by the jury. 35 U.S.C.A. §§ 102, 103.

[2] Federal Courts ⇨ 846

170Bk846 Most Cited Cases

[2] Federal Courts ⇨ 847

170Bk847 Most Cited Cases

When judgment arises from jury verdict, reviewing court applies the reasonable jury and substantial evidence standard, a standard which gives greater deference to the judgment simply because appellate review is more limited, compared with review of the trial judge's decision.

[3] Patents ⇨ 72(1)

291k72(1) Most Cited Cases

Invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference; every element of the claimed invention must be literally present, arranged as in the claim. 35 U.S.C.A. § 102.

[4] Patents ⇨ 72(1)

291k72(1) Most Cited Cases

In order for there to be anticipation, the identical invention must be shown in as complete detail as is contained in the patent claim. 35 U.S.C.A. § 102.

[5] Patents ⇨ 72(1)

291k72(1) Most Cited Cases

It was error to instruct the jury that anticipation can be shown by equivalents, a legal theory that is pertinent to obviousness, not to anticipation. 35 U.S.C.A. §§ 102, 103.

[6] Patents ⇨ 312(6)

291k312(6) Most Cited Cases

Evidence sustained finding that patent covering rear wheel suspension system for motorcycle to smooth the ride over rough terrain was not invalid for anticipation. 35

U.S.C.A. § 102.

[7] Patents ⇨ 324.55(3.1)
291k324.55(3.1) Most Cited Cases
(Formerly 291k324.55(3))

Review of jury determination as to whether challenger has proven invalidity by clear and convincing evidence is whether reasonable jurors could have concluded that the challenger failed to meet the burden.

[8] Patents ⇨ 36(3)
291k36(3) Most Cited Cases

Evidence sustained jury finding that patent on rear wheel suspension for motorcycles intended for off-road use was not invalid for obviousness. 35 U.S.C.A. § 103.

[9] Patents ⇨ 324.56
291k324.56 Most Cited Cases

Although district court erred in its belief that obviousness could only be presented to the jury for an advisory verdict, reviewing court could view the trial court's agreement with the jury verdict of validity as supporting the court's denial of posttrial motions for judgment n.o.v. and for new trial on the issue of obviousness.

[10] Patents ⇨ 312(6)
291k312(6) Most Cited Cases

Patent holder bore the burden of proving infringement by preponderance of the evidence.

[11] Patents ⇨ 314(5)
291k314(5) Most Cited Cases

Jury was the finder of fact of infringement.

[12] Patents ⇨ 314(6)
291k314(6) Most Cited Cases

Jury special verdict as to whether defendant's motorcycle rear wheel suspension infringed the plaintiff's patent which stated "yes, with the rising rate" was not a limitation of the finding of infringement to the rising rate

claim but, rather, was a response to the defendant's argument that the two suspensions were not the same because of a different rising rate.

[13] Patents ⇨ 324.56
291k324.56 Most Cited Cases

It was highly prejudicial to instruct the jury on the differences between linkages involved in patented device and allegedly infringing device while remaining silent on the similarities and to give the dictionary definition of equivalent as meaning "corresponding or virtually identical, especially in effect or function."

[14] Patents ⇨ 324.56
291k324.56 Most Cited Cases

It was prejudicial to give special verdicts in patent case which isolated specific claim elements so that it was removed from the perspective that is obtained only when the claimed invention is viewed in its entirety.

[15] Patents ⇨ 240
291k240 Most Cited Cases

Device which embodies improvements on a claimed structure does not automatically avoid the reach of the claim.

[16] Patents ⇨ 312(5)
291k312(5) Most Cited Cases

Evidence sustained finding that patent on rear wheel suspension for motorcycles intended for off-road riding was infringed.

[17] Patents ⇨ 324.55(1)
291k324.55(1) Most Cited Cases

Court reviews award of damages for patent infringement on the reasonable jury/substantial evidence standard.

[18] Patents ⇨ 324.56
291k324.56 Most Cited Cases

Court's error in instructing jury that it had found a minor infringement required reversal

of award of damages.

[19] Contracts ⇌ 353(8)
95k353(8) Most Cited Cases

It was error to instruct jury in breach of contract action in a manner which limited the scope of information which the defendant had agreed to protect more narrowly than that set forth in the contract and to instruct the jury accordingly as to the defendant's obligations under the contract.

[20] Torts ⇌ 27
379k27 Most Cited Cases

Burden of proof was on plaintiff to prove that his information met legal requirements of protectible trade secret.

[21] Torts ⇌ 27
379k27 Most Cited Cases

Evidence that contract between inventor and manufacturer stated that manufacturer agreed not to use or disclose technical information, know how, inventions, use data, and design specifications which it received from the inventor demonstrated that the information provided to the manufacturer was protectible trade secrets.

[22] Torts ⇌ 10(5)
379k10(5) Most Cited Cases

Under California law, manufacturer which received trade secrets from inventor was not entitled to use as its own any information which it could have independently discovered and fact that it could have accomplished on its own whatever the inventor contributed to it did not eliminate its liability for misappropriation of trade secrets.

[23] Torts ⇌ 10(5)
379k10(5) Most Cited Cases

Under California law, slavish copying is not necessary for misappropriation of a trade secret and independent judgment does not remove the information from protection.

[24] Patents ⇌ 1
291k1 Most Cited Cases

[24] Torts ⇌ 10(5)
379k10(5) Most Cited Cases

Legal status of information and improvements made to an invention after patent application has been filed is independent of the presence, or absence, of the patent application or ensuing patent; information and improvements may be separately patentable, they may be preserved in confidence and disclosed only in accordance with the agreement, and they are protected against misappropriation in accordance with the laws of the contract and tort.

[25] Copyrights and Intellectual Property ⇌ 104
99k104 Most Cited Cases

Information which manufacturer sought from inventor and as to which it agreed to respect confidentiality was intellectual property in the eyes of the law and protected in accordance with the law.

[26] Torts ⇌ 10(5)
379k10(5) Most Cited Cases

Inventor's design modifications to rear wheel suspension for off-road motorcycle which would extend the rear wheel travel over earlier rising-rate designs and design of an alternate mount were trade secrets.

[27] Patents ⇌ 93
291k93 Most Cited Cases

Commercial arrangement wherein inventor agreed to facilitate manufacturer's testing and evaluation of the inventor's invention did not convert the inventor's work in adapting his invention to the manufacturer's product into the work of a hired technician whose work product was automatically owned by the manufacturer.

[28] Federal Courts ⇌ 644
170Bk644 Most Cited Cases

Although there was a hint in posttrial colloquy that court intended or was willing to retry all trade secret issues, that was not sufficient to excuse plaintiff from requesting, through posttrial motion, a new trial or judgment n.o.v. on certain trade secret issues when defendant sought new trial or judgment n.o.v. with respect to other trade secrets.

[29] Federal Courts ⇌ 759.1
170Bk759.1 Most Cited Cases
(Formerly 170Bk759)

Appellate tribunal is abjured to determine whether jury verdict can be sustained on any reasonable theory.

[30] Damages ⇌ 137
115k137 Most Cited Cases

Evidence sustained jury's award of \$104,000 for motorcycle manufacturer's misappropriation of trade secrets of inventor of rear wheel suspension system.

[31] Patents ⇌ 317
291k317 Most Cited Cases

Injunction will generally issue when any patent infringement has been adjudged, absent sound reason for denying the injunction.

[32] Patents ⇌ 317
291k317 Most Cited Cases

Injunction against future patent infringement was proper where the patent would expire in less than four years, litigation had started over eight years earlier, and further proceedings could consume "several years."

[33] Injunction ⇌ 56
212k56 Most Cited Cases

Misappropriator of trade secrets has no authorization right to continue to reap the benefits of its wrongful acts, and owner of the trade secrets is entitled to injunction against continued use of the secrets by the misappropriator.

[34] Fraud ⇌ 58(1)
184k58(1) Most Cited Cases

Evidence sustained finding of fraud on the part of manufacturer which misappropriated inventor's trade secrets and infringed his patent.

[35] Federal Civil Procedure ⇌ 2338.1
170Ak2338.1 Most Cited Cases
(Formerly 170Ak2338)

New trial is not warranted simply because the district court would have reached different verdict.

[36] Fraud ⇌ 61
184k61 Most Cited Cases

Jury's assessment of punitive damages is not excluded in patent and trade secret cases where the jury expressly finds fraud.

[37] Patents ⇌ 312(7)
291k312(7) Most Cited Cases

Evidence sustained finding that plaintiff in patent infringement action was not the "real inventor" of the patent in view of evidence that he invented the patent with another and in view of contribution of third parties.

[38] Patents ⇌ 312(7)
291k312(7) Most Cited Cases

Fact that plaintiff in patent infringement action might have been only a joint inventor rather than a sole inventor did not affect issue of whether he was entitled to assignment of patent obtained by infringer of inventor's patent, as the correction of inventorship would be an administrative step, and was not before the court.

[39] Patents ⇌ 323.1
291k323.1 Most Cited Cases

Inventor claiming that he was entitled to patent obtained by infringer of his patent was not limited to remedy of interference in the United States Patent and Trademark Office and in other countries, and could obtain court

order assigning him the infringer's patent.

[40] Patents ⇌ 312(6)
291k312(6) Most Cited Cases

Jury could have found that manufacturer's infringement of inventor's patent was willful. 35 U.S.C.A. §§ 284, 285.

Patents ⇌ 328(2)
291k328(2) Most Cited Cases

4,457,393. Cited.

Patents ⇌ 328(2)
291k328(2) Most Cited Cases

3,907,332. Valid and Infringed.

***1229** Theresa A. Middlebrook, Wagner & Middlebrook, Glendale, Cal., and Robert W. Driscoll, Driscoll & Tomich, San Marino, Cal., argued for plaintiff/appellant. With them on the brief was John E. Wagner.

John A. Fogarty, Kenyon & Kenyon, New York City, argued for defendants/cross-appellants. With him on the brief were Richard S. Gresalfi and Dawn M. DiStefano. Also on the brief were Richard S. Rockwell, Tustin, Cal., Duffern H. Helsing and Halina F. Osinski, Santa Ana, Cal., of counsel.

Before SMITH, Circuit Judge, SKELTON, Senior Circuit Judge, and NEWMAN, Circuit Judge.

PAULINE NEWMAN, Circuit Judge.

This appeal and cross-appeal are from the judgment of the United States District Court for the Central District of California, and involve issues of patent validity, infringement, breach of contract, fraud, misappropriation ***1230** of trade secrets, and several related issues. [FN1] We affirm in part, reverse in part, vacate in part, and remand.

FN1. Richardson v. Suzuki Motors Co. and Suzuki U.S. Motors Corp., Nos. CV 80-2589-WPG and CV 82-3826-WPG (C.D.Cal. June 29, 1987 and July 13, 1987).

The Invention

The invention that led to this litigation is a motorcycle rear-wheel suspension system that smooths the ride over rough terrain, of interest particularly in off-road motorcycle riding. The roughness of the ride is due to bumps and dips in the terrain, transmitted from the wheels to the frame. An optimum rear-wheel suspension will maintain tire contact with the ground despite deflection by irregularities, will avoid "bottoming out" (an unsafe rising of the suspension), yet will achieve a smooth ride without reduction in safety. In 1974 even the best available suspensions did not maintain adequate tire contact with the ground in conjunction with attempts to eliminate bottoming out.

In mid-1974 Donald G. Richardson, a young mechanic in California, devised a solution to the problem, a modified suspension system that he installed in his own motocross motorcycle. Richardson replaced the conventional two-spring shock absorber suspension system with a system consisting of a single shock absorber plus a linkage consisting of a bell crank and connecting rod. This linkage generated a "rising rate" [FN2]--a characteristic critical to the issue--and produced a far superior ride, even as it eliminated the dangerous bottoming out. Richardson testified about his first ride, at a hilly construction site near his house, as "utopia. I mean it was incredible"; over hard bumps it was "uncanny because it was so smooth"; "[t]he rear end didn't kick up. It just didn't bottom out and stayed down"; an "unbelievable feeling".

FN2. "Rising rate" was described by witnesses as follows: "as the suspension travels upward, the resistance to upward travel will increase"; and it "gets stiffer as the wheel moves up toward the vehicle or moves upward in the frame."

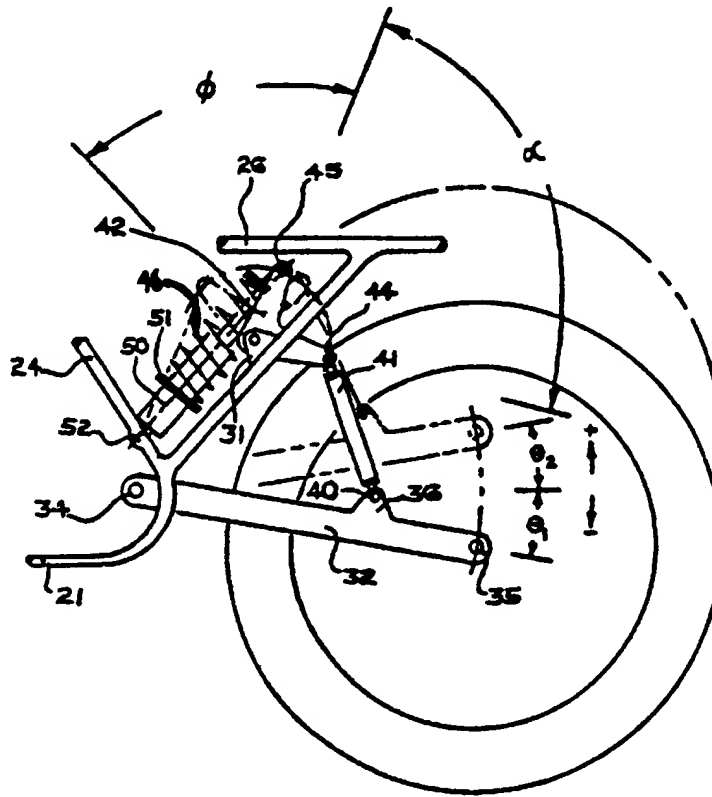
On November 25, 1974 Richardson filed a United States patent application on his invention, and on September 23, 1975 the application issued as United States Patent No. 3,907,332 (hereinafter the '332 or Richardson patent). Patent claim 9, which incorporates

claim 1, is the only claim in suit. Claims 1 and 9 follow:

1. A suspension for two wheeled vehicles comprising:
a frame for the vehicle comprising a generally closed shape including upper and lower portions and
a swing arm pivotally connected to the lower portion of said frame;
said swing arm comprising a pair of arms rotatably supporting a wheel about a horizontal axis generally at the end of said swing arm;
the pivotal mounting of said arm to said frame being about a generally horizontal axis whereby said wheel is both rotatable about its own horizontal axis and deflectable in a generally vertical direction about the axis of said swing arm;
spring means having a first end pivotally secured to said frame;
a link member including an intermediate point pivotally mounted on said frame about an axis, parallel to the axis of said swing arm at a point spaced therefrom;
pivotal connection means between said link member and the second end of said spring;
a bar pivotally connected at one end to said swing arm and at the opposite end to said link member at a position spaced from said spring connection;
said spring, bar, swing arm and link connected whereby deflection of said swing arm displaces said bar and rotates said link member to compress said spring.
9. The combination in accordance with claim 1 wherein said assembly provides a rising spring rate as a function of deflection of said swing arm.

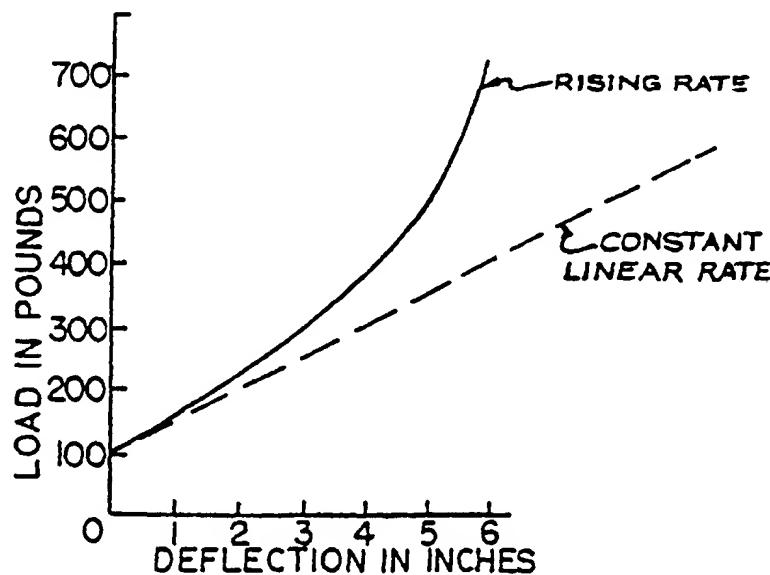
Figure 2 of the '332 patent specification is illustrative:

*1231



As the rear wheel is deflected upward by bumps in the terrain, the swing arm (32) that is pivotally connected at (34) to the motorcycle frame (21) rotates upward, pushing the compression rod (41) into the bell crank (42) that is pivotally secured (31) at its intermediate point to the motorcycle frame. The bell crank rotates on its pivot (31) and compresses, downward against the frame, a spring (46) that is pivotally connected at one end (45) to the bell crank, and at its other end (52) to the motorcycle frame. The interaction of these interconnected parts increases the force on the spring, increasing the rate of resistance to deflection of the wheel with increased movement of the wheel. This varying resistance is the "rising spring rate" of claim 9, and is illustrated in Figure 5 of the '332 patent:

*1232



The Contract with Suzuki

In October 1978 Richardson entered into a one year Option and License Agreement with the Suzuki Motor Co., Ltd. of Japan ("Suzuki").

The Agreement gave Suzuki the exclusive right to test and evaluate Richardson's suspension, and the exclusive option to acquire an exclusive license to the '332 patent and Richardson's "proprietary technical information, know-how, inventions, and use data", collectively defined in the Agreement as the "Licensed Rights."

The Agreement required Richardson to disclose to Suzuki all technical information, know-how, inventions, use data and design specifications for his suspension, that he possessed or that he acquired during the option period. Suzuki agreed to preserve all such information in confidence, and not to use any of it "for any purpose other than to evaluate for commercial feasibility of manufacture and marketing during the Option Period." Suzuki agreed that this obligation of confidence continued if Suzuki did not exercise the option. Excepted from the confidentiality obligation was all information previously known to Suzuki or at any time generally

known to the public.

The Agreement required Richardson to make prototypes of his suspension system for Suzuki's evaluation. Richardson installed his suspension in Suzuki's sample 1978 and 1979 model production motorcycles, and disclosed to Suzuki the technical information and know-how that he possessed, including improvements and other information that he developed during this period. He met frequently with Suzuki engineers and other Suzuki personnel in the United States and in Japan to communicate this information and generally to improve performance and to facilitate testing and evaluation.

There was testimony at trial of initial incredulity on the part of Suzuki engineers concerning Richardson's suspension, of Suzuki's past failures in designing a suspension with the desired characteristics, and of Suzuki's favorable response to the performance of Richardson's suspension. The evidence included internal Suzuki documents made while Suzuki was testing Richardson's suspension, stating that it would "take a long time", perhaps three years, for Suzuki to develop a satisfactory suspension.

In early 1979 Richardson and a colleague

Cazort conceived an improvement in the linkage-generated rising rate suspension, which they called the "Alternate Shock Mount" and which they disclosed to Suzuki, accompanied by drawings and blueprints *1233 made by Cazort. The difference from the structure described in the '332 patent is that in the Alternate Shock Mount the lower end of the spring is pivotally secured to the swing arm which is pivotally secured to the frame, instead of being pivotally secured directly to the frame, resulting in increased strength.

In May 1979 Richardson's first prototype for Suzuki, wherein Richardson, aided by Cazort, installed his suspension in a Suzuki 1978 production model, was successfully tested in Japan. Testimony at trial included statements attributed to Suzuki's test riders that they could see the bumps but not feel them, and other commentary evidencing a highly favorable reaction to Richardson's suspension.

It was a stipulated fact that after these tests Suzuki made the decision to place the linkage-generated rising rate suspension system into production, and started development work for this purpose.

On October 16, 1979 Suzuki filed a patent application in Japan. The corresponding United States patent, filed on October 8, 1980, claims the Alternate Shock Mount suspension as disclosed by Richardson, and also claims a modification made by Suzuki called the "criss-cross". Suzuki named two of its engineers, Hirohide Tamaki and Manabu Suzuki, as the inventors.

Suzuki twice requested and was granted one-month extensions of its Option and License Agreement with Richardson. In December 1979 Suzuki informed Richardson that it would not exercise the option.

In March 1980 Suzuki began competitive racing in the United States of Suzuki motorcycles using the Alternate Shock Mount suspension, which Suzuki named the "Full Floater". Suzuki met with marked racing

success, the Full Floater receiving favorable publicity and high acclaim from the public. Extensive advertising was directed to the Full Floater rising rate suspension. The product achieved widespread commercial success.

Suzuki denied any obligation to Richardson.

Litigation

Richardson brought suit against Suzuki (Japan) and the U.S. Suzuki Motor Corporation in California state court, and was granted a preliminary injunction restraining the Suzuki companies from breach of the Option and License Agreement and requiring them to comply with the confidentiality terms thereof. At Suzuki's request the state court declined to enforce the injunction after U.S. Suzuki sued Richardson in federal court, seeking a declaratory judgment of invalidity and non-infringement of Richardson's '332 patent.

In 1982 Richardson filed a patent infringement action against the Suzuki companies and others. (Only the Suzuki companies remain as parties.) Richardson reasserted the state claims of breach of contract, breach of implied covenant of good faith and fair dealing, misappropriation of trade secrets, and fraud, and among other relief requested assignment of the patents obtained by Suzuki on the Alternate Shock Mount. Suzuki counterclaimed for fraud and breach of contract by Richardson, based on asserted invalidity of the '332 patent.

The federal actions were consolidated and tried to a jury. After forty-seven days of a two-part trial the jury gave special verdicts on issues of liability and damages. The district court entered final judgment under Fed.R.Civ.P. 54(b) on the jury verdicts that the '332 patent was not invalid and was infringed by Suzuki, that nine of Richardson's eleven asserted trade secrets were not trade secrets, and that Richardson was not entitled to assignment of the Tamaki/Suzuki patents on the Alternate Shock Mount. The court also entered final judgment on the jury verdicts of damages for patent infringement

and for Suzuki's use of certain of Richardson's information that the jury found were not trade secrets. The court denied prejudgment interest and attorney fees, and refused to grant an injunction.

The district court denied most of the parties' post-trial motions, but granted Suzuki's motion for a new trial on three issues that the jury had decided in favor of *1234 Richardson, upholding two of the eleven asserted trade secrets, finding fraud on the part of Suzuki, and assessing damages for fraud. The district court then entered a supplemental final judgment for immediate appeal of the issues that the court intended to retry, and certified three specific questions on these and related issues.

I

Validity of Richardson's '332 Patent

Suzuki asserts on appeal the invalidity of claim 9 on grounds of anticipation (35 U.S.C. § 102) and obviousness (35 U.S.C. § 103). [FN3] The district court, stating that questions of patent validity must be decided by the court, told the jury that its verdicts on this issue were advisory. Nevertheless the court duly entered the jury verdicts, including the answer YES to the question: "Under the facts and law as you believe that you understand them, do you find Claim 9 of the Richardson Patent to be valid?" The court entertained, and denied, post-trial motions for judgment n.o.v. and for a new trial on the question of validity. The court also independently decided the question, upholding validity of the '332 patent.

FN3. The additional aspects of adequacy of disclosure (35 U.S.C. § 112) and unenforceability for inequitable conduct, both decided in favor of Richardson, have not been appealed.

The record provided to us doesn't show the origin of this discredited procedure of advisory verdicts, or whether either party objected. In *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 895 n. 5, 221 USPQ 669, 674 n. 5, (Fed.Cir.), *cert. denied*, 469 U.S. 857, 105 S.Ct. 187, 83 L.Ed.2d 120 (1984), we observed that:

The view suggested in *Sarkisian [v. Winn-Proof Corp.]*, 688 F.2d 647, 651, (9th Cir.1982), *cert. denied*, 460 U.S. 1052 [103 S.Ct. 1499, 75 L.Ed.2d 930] (1983)], that a jury verdict on nonobviousness is at best advisory, would make charades of motions for directed verdict or JNOV under Fed.R.Civ.P. 50 in patent cases. These motions apply only to *binding* jury verdicts....

Moreover, use of an advisory jury is limited to actions not triable of right by a jury.

(emphasis in original, citations omitted). In a similar circumstance wherein the trial court and the jury independently decided the same jury question (in that case the question of willfulness of infringement) we remarked that "[a]ll fact findings of a jury are non-advisory, unless made in an area expressly removed from jury verdict." *Shiley, Inc. v. Bentley Laboratories, Inc.*, 794 F.2d 1561, 1568, 230 USPQ 112, 115 (Fed.Cir.1986), *cert. denied*, 479 U.S. 1087, 107 S.Ct. 1291, 94 L.Ed.2d 148 (1987).

[1] It is established that the jury may decide the questions of anticipation and obviousness, either as separate special verdicts or en route to a verdict on the question of validity, which may also be decided by the jury. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1547, 220 USPQ 193, 197 (Fed.Cir.1983):

No warrant appears for distinguishing the submission of legal questions to a jury in patent cases from such submissions routinely made in other types of cases. So long as the Seventh Amendment stands, the right to a jury trial should not be rationed, nor should particular issues in particular types of cases be treated differently from similar issues in other types of cases.

See also, e.g., Vieau v. Japax, Inc., 823 F.2d 1510, 1515, 3 USPQ2d 1094, 1098 (Fed.Cir.1987); *Verdegaal Brothers Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1052 (Fed.Cir.), *cert. denied*, 484 U.S. 827, 108 S.Ct. 95, 98 L.Ed.2d 56 (1987); *Data Line Corp. v. Micro Technologies, Inc.*, 813 F.2d 1196, 1200, 1 USPQ2d 2052, 2054 (Fed.Cir.1987); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1571, 1 USPQ2d 1081, 1085 (Fed.Cir.1986); *DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 425-27, 231

USPQ 276, 279-80 (Fed.Cir.1986); *Mainland Industries, Inc. v. Standal's Patents Ltd.*, 799 F.2d 746, 747-48, 230 USPQ 772, 773 (Fed.Cir.1986); *Trans-World Mfg. Corp. v. Al *1235 Nyman & Sons, Inc.*, 750 F.2d 1552, 1560, 224 USPQ 259, 263 (Fed.Cir.1984); *Quaker City Gear Works, Inc. v. Skil Corp.*, 747 F.2d 1446, 1454-55, 223 USPQ 1161, 1165-66 (Fed.Cir.1984), *cert. denied*, 471 U.S. 1136, 105 S.Ct. 2676, 86 L.Ed.2d 694 (1985); *Weinar v. Rollform Inc.*, 744 F.2d 797, 805, 223 USPQ 369, 372 (Fed.Cir.1984), *cert. denied*, 470 U.S. 1084, 105 S.Ct. 1844, 85 L.Ed.2d 143 (1985); *Perkin-Elmer Corp.*, 732 F.2d at 894-95, 221 USPQ at 674; *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758, 221 USPQ 473, 477 (Fed.Cir.1984); *Railroad Dynamics, Inc. v. A. Stucki Company*, 727 F.2d 1506, 1512-13, 220 USPQ 929, 935 (Fed.Cir.), *cert. denied*, 469 U.S. 871, 105 S.Ct. 220, 83 L.Ed.2d 150 (1984); *White v. Jeffrey Mining Mach. Co.*, 723 F.2d 1553, 1558, 220 USPQ 703, 705 (Fed.Cir.1983) ("Submission of such a question of law [obviousness] to a jury, accompanied by appropriate instructions, is proper."), *cert. denied*, 469 U.S. 825, 105 S.Ct. 104, 83 L.Ed.2d 49 (1984). See generally H.T. Markey in *On Simplifying Patent Trials*, 116 F.R.D. 369, 370 (1987) ("There is neither reason nor authority for employing in a patent trial procedures and practices different from those employed in any other civil trial. Indeed, reason and authority mandate the contrary.")

[2] Although the district court and the jury reached the same result, the standards by which appellate courts review the judgment differ, depending on whether it arose from a jury or a bench trial. *District of Columbia v. Pace*, 320 U.S. 698, 701, 64 S.Ct. 406, 408, 88 L.Ed. 408 (1944) ("findings of fact by an equity court and the verdict of a jury have from time immemorial been subject to different rules of finality"). When the judgment arises from a jury verdict, the reviewing court applies the reasonable jury/substantial evidence standard: a standard that gives greater deference to the judgment simply because appellate review is more limited, compared with review of a trial judge's decision. *Id.* at 702, 64 S.Ct. at 408. As summarized in *Lavender v. Kurn*, 327 U.S. 645, 653, 66 S.Ct. 740, 744, 90 L.Ed. 916

(1946), "the appellate court's function is exhausted when that evidentiary basis [of the jury's verdict] becomes apparent, it being immaterial that the court might draw a contrary inference or feel that another conclusion is more reasonable." See generally M.B. Louis, *Allocating Adjudicative Decision Making Authority Between the Trial and Appellate Levels: A Unified View of the Scope of Review, The Judge/Jury Question, and Procedural Discretion*, 64 N.C.L.Rev. 993 (1986).

The parties do not take a position on the district court's procedure, but appear to recognize that the issue of validity was properly for jury determination, for neither party refers to the district court's explanation of its independent determination of the question of obviousness.

In the interest of reaching an end to this protracted litigation, we have reviewed the judgment on the terms on which it reaches us. We have determined first whether Suzuki met its burden of showing on appeal that no reasonable jury could have reached the verdict of "valid" on the evidence before it. *Allen Organ Co. v. Kimball Int'l, Inc.*, 839 F.2d 1556, 1566, 5 USPQ2d 1769, 1777 (Fed.Cir.), *cert. denied*, 488 U.S. 850, 109 S.Ct. 132, 102 L.Ed.2d 104 (1988); *DML, Inc. v. Deere & Co.*, 802 F.2d 421, 425, 231 USPQ 276, 278 (Fed.Cir.1986); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 618-19, 225 USPQ 634, 636 (Fed.Cir.), *cert. dismissed*, 474 U.S. 976, 106 S.Ct. 340, 88 L.Ed.2d 326 (1985). Then, on the premise that the parties may have waived their right to a jury trial on this question by failure to object to the district court's procedure, we have considered whether the district court's independent judgment of validity may be sustained, on the standards applicable thereto. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566-68, 1 USPQ2d 1593, 1595-97 (Fed.Cir.) (obviousness determination in bench trial reviewed as a question of law based on underlying facts), *cert. denied*, 481 U.S. 1052, 107 S.Ct. 2187, 95 L.Ed.2d 843 (1987).

The court correctly instructed the jury that invalidity must be proved by clear and

convincing evidence, referring to the presumption of validity. *Perkin-Elmer *1236 Corp.*, 732 F.2d at 894, 221 USPQ at 674; *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 756 F.2d 1556, 1559, 225 USPQ 253, 255 (Fed.Cir.1985); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 771 (Fed.Cir.), cert. denied, 469 U.S. 821, 105 S.Ct. 95, 83 L.Ed.2d 41 (1984).

A. Anticipation

[3][4] The district court correctly instructed the jury that an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim. *Perkin-Elmer Corp.*, 732 F.2d at 894, 221 USPQ at 673; *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771-72, 218 USPQ 781, 789 (Fed.Cir.1983), cert. denied, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984). The identical invention must be shown in as complete detail as is contained in the patent claim. *Jamesbury Corp.*, 756 F.2d at 1560, 225 USPQ at 256; *Connell*, 722 F.2d at 1548, 220 USPQ at 198.

As prior art, Suzuki relied on the motorcycle suspensions described in certain patents to Downs and Warner, and on the race car wheel suspensions described for Tyrrell and McLaren race cars in two Road and Track magazine articles. Witnesses explained to the jury the similarities and differences between the invention of the '332 patent and each prior art reference. For example, the Downs suspension has a spring element that is rigidly attached to the motorcycle frame and does not pivot as is required by claim 9 of the '332 patent. The Warner reference shows a suspension having a bell crank that is pivotally mounted to the motorcycle frame but not at an intermediate point, whereas Richardson requires a mid-point pivot of the bell crank to the frame. Neither Downs nor Warner describes a rising rate. The magazine articles describe a four wheel racing car suspension system having a linkage-generated variable rising rate incorporating a bell crank, but instead of the swing arm of Richardson's

motorcycle suspension, the race car systems use an A-shaped arm mounted to the side of an upright wheel; and the bell crank and linkage in the race car system is located beside the wheel, rather than in front of the wheel as in Richardson's motorcycle system.

Witnesses testified that rising rate in motorcycles had previously been obtained only by progressively wound springs and gas operated shock absorbers. Suzuki argued that rising rate is inherent in the Downs and Warner motorcycle suspensions and expressly described for race cars in the magazine articles, and also that rising rate is merely a statement of function, and thus should not be a basis for distinction from the prior art.

The jury found that Downs did not "disclose each and every element of the Richardson Claims 1 and 9 or their equivalent". For the Warner reference, the jury could not reach a unanimous verdict on this same question, but answered NO to the question whether "the respective elements of Warner function in substantially the same way as the corresponding elements in Richardson to produce substantially the same results". The jury found that the race car suspensions did "disclose each and every element of the Richardson Claims 1 and 9 or their equivalent", but did not reach a unanimous verdict as to whether they "function in substantially the same way as the corresponding elements in Richardson to produce substantially the same results."

[5] The jury had erroneously been instructed that anticipation may be shown by equivalents, a legal theory that is pertinent to obviousness under Section 103, not to anticipation under Section 102. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747-48, 3 USPQ2d 1766, 1768 (Fed.Cir.1987), cert. denied, 484 U.S. 1007, 108 S.Ct. 702, 98 L.Ed.2d 653 (1988); *Connell*, 722 F.2d at 1548, 220 USPQ at 198. The jury requested a definition of "equivalent" during its deliberations, and was given the Webster's dictionary definition "corresponding or virtually identical, especially in effect or function." This narrow definition, which does

not accord with that of *Graver Tank & Mfg. Co. v. Linde Air *1237 Products Co.*, 339 U.S. 605, 608, 70 S.Ct. 854, 856, 94 L.Ed. 1097 (1950), may have minimized the legal error in the instructions. In any event, the erroneous inclusion of equivalents in the anticipation inquiry favored Suzuki. The jury nonetheless answered YES to the special verdict: "Under the facts and law as you believe that you understand them, do you find Claim 9 of the Richardson Patent to be valid?"

[6] On the totality of the evidence and in light of the jury instructions and answers, we conclude that a reasonable jury could have found that the patent was not invalid on grounds of anticipation. *Perkin-Elmer Corp.*, 732 F.2d at 894, 221 USPQ at 673-74 (review of presumed jury finding that anticipation not proved, based on jury verdict of validity).

Reviewing the analysis and decision of the district court, based on the same prior art, we discern no clear error in the court's conclusion that claim 9 was not invalid.

We affirm that claim 9 was not proved invalid on the ground of anticipation.

B. Obviousness

The issue of obviousness was vigorously litigated, Suzuki relying on the same Downs and Warner patents and magazine articles. The record shows that there was extensive testimony concerning the differences between Richardson's suspension and the prior art. Suzuki argued at trial, and repeats on this appeal, that these differences are trivial mechanical expedients.

The jury, among its special verdicts on the *Graham* factors, found that a person of ordinary skill in the pertinent art could be any of: (1) a motorcycle mechanic without formal technical education, (2) a person with experience in working on suspension systems for racing automobiles, but without formal technical training, (3) suspension system instructors, (4) professional motorcycle riders, and (5) someone possessing above-average mechanical skills. Suzuki argues that such a person is of

generally high mechanical skill, and to such a person Richardson's rising rate motorcycle suspension would have been an obvious "adaption" of the race car suspension systems, which "suggests itself quite plainly, since Downs and Warner incorporate bell cranks in their respective suspensions."

The jury was unable to reach a unanimous verdict on the question of whether a person of the level of skill found by the jury, presented with the problem and being familiar with all the prior art including these four specific references, but unaware of Richardson's device, would be "led to do" what Richardson did. In response to the ultimate question, as we have observed, the jury reached the unanimous verdict that "Under the facts and law as you believe that you understand them", claim 9 was "valid". The district court entered judgment on the jury verdicts, independently held the patent valid, and denied Suzuki's motions for judgment n.o.v. and for a new trial on the issue of validity.

[7] The question for the jury was whether the challenger met the burden of proving invalidity by clear and convincing evidence; and the question on review is whether reasonable jurors could have concluded that the challenger failed to meet that burden. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1571, 1 USPQ2d 1081, 1085 (Fed.Cir.1986); *Perkin-Elmer Corp.*, 732 F.2d at 894-95, 221 USPQ at 674. The jury's lack of unanimity on certain special verdicts can reasonably be taken to mean, as the district court held, that invalidity had not been proved by clear and convincing evidence.

[8][9] Our review shows that there was substantial evidence on which reasonable jurors could have concluded that claim 9 had not been proved invalid for obviousness, and thus reached the verdict of "valid". Although the district court erred in its belief that obviousness could only be presented to the jury for an advisory verdict, we may view the court's agreement with the jury verdict of validity as supporting the court's denial of Suzuki's post-trial motions for judgment n.o.v. and for a new trial. *Perkin-Elmer Corp.*,

732 F.2d at 895, 221 USPQ at 674-75. However it is viewed procedurally, no reversible error *1238 has been shown in the court's conclusion that obviousness had not been proved and that claim 9 was not invalid.

The judgment of validity is affirmed.

II Infringement

[10][11] Richardson bore the burden of proving infringement by a preponderance of the evidence. The district court correctly stated that the jury was the finder of the fact of infringement.

[12] The jury rendered special verdicts as to the Suzuki motorcycles before it, Model M having the Richardson/Cazort Alternate Shock Mount and Model C having the "criss-cross" connection added by Suzuki, as follows:

9(a). Do defendant Suzuki's motorcycles of the Model M type ... infringe Claim 9 of the plaintiff's patent?

Answer: YES, WITH THE RISING RATE

9(b). Do defendant Suzuki's motorcycles of the Model C type ... infringe Claim 9 of the plaintiff's patent?

Answer: YES, WITH THE RISING RATE

In subparts 9(a)(2) and 9(b)(2) of the special verdict the jury answered YES to the question whether the Suzuki motorcycles produce substantially the same rising rate as taught in Richardson's patent.

The principal question on appeal is the meaning and effect of the jury answers to subparts (1) of the special verdict, which were directed "in particular" to the Alternate Shock Mount and the criss-cross modifications:

9(a)(1). In particular, is the defendant's linkage equivalent to the plaintiff's, bearing in mind that the bottom of the spring in the former is affixed to the swing arm rather than to the frame?

Answer: NO

9(b)(1). In particular, is the defendant's linkage equivalent to the plaintiff's, in light of the "criss-cross" of the connecting rods and the bell crank in the defendant's model, as well as the spring attachment to the swing

arm, as compared with the plaintiff's Claim 9?

Answer: NO

The district court entered judgment of infringement in favor of Richardson and denied post-trial motions by both sides, including a motion by Richardson to reopen the record in order to present evidence on the doctrine of equivalents. The district court stated that the jury verdicts mean that "infringement is limited to 'rising rate' " and that the Suzuki and Richardson linkages are not equivalent.

Suzuki argues that special verdicts 9(a)(1) and 9(b)(1) require judgment of non-infringement; or, as a minimum, that these verdicts are inconsistent with the verdicts of infringement in 9(a) and 9(b), such that a new trial is required of the entire issue. Richardson states that the verdicts can be understood, when viewed in light of the jury instructions, in a way that supports the judgments of infringement. Suzuki did not request a new trial on the basis of inconsistent verdicts at the time the judgments were entered, while Richardson moved, unsuccessfully, to amend or delete verdicts 9(a)(1) and 9(b)(1). Each party asserts that any inconsistency should be resolved in its favor.

The Ninth Circuit, in accordance with the general rule, requires trial and appellate courts to seek reconciliation of apparently inconsistent verdicts:

When faced with a claim that verdicts are inconsistent, the court must search for a reasonable way to read the verdicts as expressing a coherent view of the case, and must exhaust this effort before it is free to disregard the jury's verdict and remand the case for a new trial.

Toner v. Lederle Laboratories, 828 F.2d 510, 512 (9th Cir.1987), cert. denied, 485 U.S. 942, 108 S.Ct. 1122, 99 L.Ed.2d 282 (1988) (citing *Gallick v. Baltimore & Ohio R.R.*, 372 U.S. 108, 119, 83 S.Ct. 659, 666, 9 L.Ed.2d 618 (1963), also citing *Atlantic & Gulf Stevedores, Inc. v. Ellerman Lines, Ltd.*, 369 U.S. 355, 364, 82 S.Ct. 780, 786, 7 L.Ed.2d 798 (1962) and *Blanton v. Mobil Oil Corp.*, 721 F.2d 1207, 1213, (9th

Cir.1983), *cert. denied*, 471 U.S. 1007, 105 S.Ct. *1239 1874, 85 L.Ed.2d 166 (1985)). See also *Allen Organ Co.*, 839 F.2d at 1563, 5 USPQ2d at 1775 (the appellate court must make every effort to harmonize the jury's answers).

The district court did not find the special verdicts inconsistent, apparently in the belief that the jury limited infringement to the rising rate provision of claim 9 but not the other claim clauses. This accords with the court's statement to the jury that the infringement was "minor" because it was limited to the rising rate. This interpretation pleased neither party. If we have correctly understood it, it is incorrect as a matter of law.

"We are bound to find the special verdicts consistent if we can do so under a fair reading of them." *Toner*, 828 F.2d at 512. A fair reading of the special verdicts results from simply applying the rule that "[t]he consistency of the jury verdicts must be considered in light of the judge's instructions to the jury". *Toner*, 828 F.2d at 512. The instructions on infringement, and the specific questions asked by special verdict, were designed to resolve the issues raised at trial. There was testimony on both sides of Suzuki's assertion that its suspension was not the same as Richardson's because it produced a different rising rate. We referred *supra* to special verdicts 9(a)(2) and 9(b)(2):

9(a)(2). Does defendant's Model M produce rising rate substantially the same as the rising rate produced under the teachings of the plaintiff's patent?

Answer: YES

9(b)(2). Does defendant's Model C produce rising rate substantially the same as the rising rate produced under the teachings of the plaintiff's patent?

Answer: YES

Another special verdict in the infringement section asked the jury:

11. Does claim 9 of the Richardson Patent describe the invention of a rising rate in terms of what the invention will do rather than in terms of physical arrangement?

Answer: NO

We conclude that the answer "yes, with the rising rate" in verdicts 9(a) and 9(b) is the jury's response to Suzuki's argument, rather than as a finding that only the rising rate claim limitation, and no other, is embodied in the Suzuki suspensions.

We discern no support in the record for the district court's conclusion that verdicts 9(a) and 9(b) meant that the rising rate was the only area of infringement. Structure corresponding to every element of every clause of claims 1 and 9 was identified by witnesses as embodied in the accused motorcycles. There was no real dispute that of the nine or eleven elements in these claims (depending on how counted), all but one were literally present. The dispute centered on one element, the attachment of the spring in the claim clause "spring means having a first end pivotally secured to said frame", since this was the clause affected by the modifications of the Alternate Shock Mount and the criss-cross. In the Alternate Shock Mount, as we have discussed, the spring is pivotally secured to a swing arm that in turn is pivotally secured to the frame, instead of being pivotally secured directly to the frame as is shown in the '332 specification.

Richardson argues that the spring can be either directly or indirectly pivotally secured to the frame, without avoiding literal infringement of the claim. Richardson alternatively argues that on a correct definition of the doctrine of equivalents, citing *Graver Tank*, 339 U.S. at 608, 70 S.Ct. at 856, these securements are equivalent because the structures are substantially the same and perform substantially the same function in the same way.

The jury had been given the dictionary definition that "equivalent" means "corresponding or virtually identical, especially in effect or function". This definition was reinforced by the phrasing of verdicts 9(a)(1) and 9(b)(1), wherein the question itself instructed the jury on the difference between the linkages, while remaining silent on the similarities.

[13] This presentation was highly prejudicial. Indeed, these verdicts well illustrate the truism that the way a question is *1240 asked can direct the answer. "The decision to submit interrogatories, and the precise language in which they are couched, can have an untoward effect on a verdict, if certain elements of the trial or the evidence are thereby overly emphasized in the jury's mind." *Weinar v. Rollform Inc.*, 744 F.2d 797, 809, 223 USPQ 369, 376 (Fed.Cir.1984), cert. denied, 470 U.S. 1084, 105 S.Ct. 1844, 85 L.Ed.2d 143 (1985).

[14] Further, and equally prejudicial, special verdicts 9(a)(1) and 9(b)(1) isolated this specific claim element so that it was removed from the perspective that is obtained only when the claimed invention is viewed in its entirety. See, e.g., *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1363, 219 USPQ 473, 482 (Fed.Cir.1983). We recently reemphasized in *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1253 (Fed.Cir.1989), in discussing *Graver Tank*, that there is no error in considering "the principle of the claimed invention".

[15] A device that embodies improvements on a claimed structure does not automatically avoid the reach of the claim. See, e.g., *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1580, 224 USPQ 409, 417 (Fed.Cir.1984) (separately patentable improvement may also be an equivalent under the doctrine of equivalents); *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703, 218 USPQ 965, 967-68 (Fed.Cir.1983) (infringement not avoided "merely by adding elements"), cert. denied, 464 U.S. 1042, 104 S.Ct. 707, 79 L.Ed.2d 171 (1984). Each case must be decided on its particular facts, viewing the changes in the accused structure in light of the claimed invention. See generally *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934-35, 4 USPQ2d 1737, 1739 (Fed.Cir.1987), cert. denied, 485 U.S. 961, 108 S.Ct. 1226, 99 L.Ed.2d 426 (1988), and cert. denied, 485 U.S. 1009, 108 S.Ct. 1474, 99 L.Ed.2d 703 (1988); *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1569-70, 231 USPQ 833, 840 (Fed.Cir.1986), reh'g denied, 846 F.2d

1369, 6 USPQ2d 1886 (Fed.Cir.1988).

[16] We conclude that the jury verdicts, viewed in light of the instructions, held that the Suzuki motorcycles with a rising rate infringed claim 9. We also conclude that on correct instructions no reasonable jury could have found that the claimed invention and the accused structures are not equivalent, on the established facts of record, applying the correct law of *Graver Tank*. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 106 S.Ct. 2505, 2512, 91 L.Ed.2d 202 (1986) ("The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff."); *Pullman-Standard v. Swint*, 456 U.S. 273, 291-92, 102 S.Ct. 1781, 1791-92, 72 L.Ed.2d 66 (1982) ("where findings [by the district court] are infirm because of an erroneous view of the law, a remand is the proper course unless the record permits only one resolution of the factual issue"); *Dana Corp. v. IPC Limited Partnership*, 860 F.2d 415, 419, 8 USPQ2d 1692, 1696 (Fed.Cir.1988) (when there are sufficient established facts of record, appellate court has discretion to determine the merits of JNOV motion.)

The jury verdicts of infringement are supported by substantial evidence, and are upheld. The judgment of infringement is affirmed.

III

Damages for Patent Infringement

[17] As damages for patent infringement the jury assessed a royalty of fifty cents per motorcycle. Richardson states that this royalty is unreasonably low, and resulted from erroneous and prejudicial jury instructions. We review the award on the reasonable jury/substantial evidence standard. *Shatterproof Glass Corp.*, 758 F.2d at 627-28, 225 USPQ at 643-44.

[18] The court told the jury: "Now, I will sustain, I will uphold your verdict [of infringement], but in determining damages and determining any royalty, it seems to me

that you must consider that the infringement was a relatively minor infringement." *1241 This instruction derived, as we have discussed, from the erroneous interpretation of the verdicts as limited to the "rising rate" clause. We must determine whether this erroneous instruction was prejudicial to the jury's assessment of damages. The Ninth Circuit has stated that "we will reverse a judgment because of a mistake in jury instructions only if the error was prejudicial." *Smiddy v. Varney*, 665 F.2d 261, 265 (9th Cir.1981), cert. denied, 459 U.S. 829, 103 S.Ct. 65, 74 L.Ed.2d 66 (1982).

35 U.S.C. § 284 provides that damages shall be "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer". *Fromson v. Western Litho Plate and Supply Co.*, 853 F.2d 1568, 1574, 7 USPQ2d 1606, 1612 (Fed.Cir.1988). The jury was told that a royalty of \$2.00 per motorcycle with an annual minimum of \$70,000 had been agreed to by Suzuki and Richardson in the Option and License Agreement. There was testimony of much higher royalties paid by others for similar contributions to motorcycles. Suzuki presented testimony that the \$2.00 in the agreement does not apply, but should be the starting point for reducing the royalty because the infringement was minor.

We must assume that the jury followed the court's instruction that the infringement was minor. That instruction was a misinterpretation of the jury verdict of infringement, and it usurped the role of the jury. Absent this prejudicial instruction there was no reasonable basis on which reasonable jury could have found that fifty cents was a reasonable royalty.

The judgment of damages for patent infringement is vacated. We remand for retrial of the question.

IV

Richardson's Technical Information

Issues relating to Richardson's technical

information were presented at trial on the legal theories of breach of contract and the tort of misappropriation of trade secrets. The district court concentrated the tort issues in presentation to the jury, apparently accepting Suzuki's position that it had complied with its contractual obligations to Richardson. The court thus required that Richardson prove the existence of legally protectible trade secrets and their misappropriation by Suzuki.

In the only special verdict on the contract issues, the jury found that Suzuki did not violate its duty of good faith and fair dealing in its relationship with Richardson. The jury instructions on the contractual relationship, however, are pertinent to, and intertwined with, the trade secret issues.

A. The Contractual Relationship

[19] In matters of contract law and interpretation we apply the discernable law of the state of California. *Universal Gym Equipment, Inc. v. ERWA Exercise Equipment Ltd.*, 827 F.2d 1542, 1550, 4 USPQ2d 1035, 1040 (Fed.Cir.1987). At trial Richardson pressed, unsuccessfully, the California law that a covenant of good faith and fair dealing is implied between parties to a contract. *Seaman's Direct Buying Service, Inc. v. Standard Oil Co.*, 36 Cal.3d 752, 768, 686 P.2d 1158, 1166, 206 Cal.Rptr. 354, 363 (1984) ("It is well settled that, in California, the law implies in every contract a covenant of good faith and fair dealing." (Emphasis in original)).

The contract between Richardson and Suzuki was explained at trial, including the clause wherein Suzuki agreed not to use or disclose the "technical information, know-how, inventions, use data, and design specifications" that it received from Richardson. In discussing whether Suzuki was restrained in its post-contract use of Richardson's information, the district court at first instructed the jury that Suzuki was entitled by law "to use the most efficient means, even though they got it from plaintiff", stating that only "valid trade secrets" were subject to the contractual restraints:

And then after Suzuki's election not to take a

license, of course, they were not supposed to use the plaintiff's trade secrets. That's what the contract says. And once again, you're going to have to determine whether these eleven were val*1242 id trade secrets. To what extent did the defendant use them, to what extent would the defendant otherwise have developed them.

Now, some of these trade secrets refer to the best alignments and designs. Well, it seems incongruous to say to the defendant they cannot use the best because the best was intentionally disclosed by the plaintiff, and even though experimentation by the defendant surely would have revealed the best as the patent says that it would.

Were the defendants precluded from using the best or were they obliged to use something less efficient. I can't conceive of the defendants not being entitled to use the most efficient means, even though they got it from the plaintiff.

The court later qualified this position by referring to reverse engineering as being improper-although it is far from clear what a reasonable jury would have understood from the court's instructions:

But on further reflection, I have to acknowledge that if you find there was a confidential relationship or contract that prohibited Suzuki from using the plaintiff's trade secrets, technical information or know-how, inventions or use data that the plaintiff gave them, unless it exercised the option, if you find those things to be true, I suppose it would be improper for Suzuki to reverse engineer from Richardson's prototypes, or from trade secrets or other information that he gave them.

The defense of reverse engineering does not apply to information received in confidence or whereas here the information is given under a contract.

Reviewing these instructions in the context of the contract and trade secret questions that were before the jury, we conclude that the jury was incorrectly instructed on the law. See *Bulgo v. Munoz*, 853 F.2d 710, 714 (9th Cir.1988) (quoting *Los Angeles Memorial Coliseum Comm'n v. National Football League*, 726 F.2d 1381, 1398 (9th Cir.), cert. denied, 469 U.S. 990, 105 S.Ct. 397, 83 L.Ed.2d 331 (1984))

(instructions reviewed to determine "whether, viewing the jury instructions as a whole, the trial judge gave adequate instructions on each element of the case to ensure that the jury fully understood the issues.")

In *Universal Gym Equipment*, 827 F.2d at 1549, 4 USPQ2d at 1040, we affirmed liability under California law based on breach of contract, when the parties contracted to limit the use by the recipient of "features, designs, technical information, or know-how" disclosed under the contract. We also affirmed that such a contractual arrangement is not incompatible with the patent law, *id.* at 1550, 4 USPQ at 1041, an issue on which the district court in Richardson's case also appears to have been misled, and to have misled the jury. See *Components for Research, Inc. v. Isolation Products, Inc.*, 241 Cal.App.2d 726, 730, 50 Cal.Rptr. 829, 832 (1966) ("The judgment here but affords protection against the use of plaintiff's trade secrets by those to whom they had been disclosed in confidence. Whether the idea was patented or not, plaintiff is entitled to such protection").

The district court erred in law, in limiting the scope of protected information beyond that set forth in the contract, and in its instructions to the jury as to Suzuki's obligations. These errors are reflected in the trade secret issues.

B. The trade secret issues

The jury, despite the excessively restrictive instructions on what were trade secrets, found that certain items that Suzuki had received from Richardson were trade secrets and had been misappropriated, and assessed damages therefor. The jury also assessed damages for use by Suzuki of certain other items that did not "rise to the dignity of trade secrets", in the words of the special verdicts.

Richardson specified eleven items that he had disclosed to Suzuki under the contract, and that he asserted to be trade secrets; to wit: (1) the optimal characteristics of a motorcycle rear-wheel suspension shock absorber, showing three external adjustments, (2) engineering drawings of his proposed and

furnished suspension systems, *1243 (3) 1978 and 1979 Suzuki motorcycles modified by Richardson with his rising rate suspension, (4) specific force-velocity curves needed to obtain the advantages of Richardson's invention in Suzuki's motorcycles, (5) design modifications to extend rear wheel travel over earlier rising-rate designs, (6) design of the Alternate Shock Mount including drawings and knowhow, (7) the optimum use and types of certain bearings in the suspension, (8) motorcycle testing and tuning criteria, (9) his bell crank designs and design criteria, (10) adjustments in the angles and dimensions of the parts of the suspension and their effect on performance, and (11) the straight line tubular motorcycle frame.

The California law of trade secrets follows the Restatement definition:

A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.... Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article.

By-Buk Co. v. Printed Cellophane Tape Co., 163 Cal.App.2d 157 at 166, 329 P.2d 147 at 152, 118 USPQ 550 at 553, (1958) citing Restatement (First) of Torts, § 757 comment b (1939). The court in *By-Buk Co.* reaffirmed "plaintiff's right not to have its [trade secret] processes wrongfully disclosed to others and used to its detriment." *Id.* at 167, 329 P.2d at 153, 118 USPQ at 553.

[20][21] The burden of proof was placed on Richardson to prove that his information met the legal requirements of a protectible trade secret. *Forro Precision, Inc. v. International Business Machines Corp.*, 673 F.2d 1045, 1056-57, 215 USPQ 299, 305-6 (9th Cir.1982). This in turn required "either a covenant or a confidential relationship" as a premise of relief. *Futurecraft Corp. v. Clary Corp.*, 205 Cal.App.2d 279, 283, 23 Cal.Rptr. 198, 207-08 (1962) (discussing elements of trade secret protection). Richardson met this requirement through his contractual covenant.

[22] The district court told the jury, several times, that because Suzuki might have developed or could have developed on its own the information it received from Richardson, such information can not be protected as a trade secret. The court said: "Now I think we must assume that the defendant could have accomplished whatever the plaintiff may have contributed toward the development of Models M and C." Whatever the validity of the proposed assumption as to Suzuki's abilities, the court's conclusion is contrary to California law:

It is not necessary in order that a process of manufacture be a trade secret that it be patentable or be something that could not be discovered by others by their own labor and ingenuity.

By-Buk Co., 163 Cal.App.2d at 166, 329 P.2d at 152, 118 USPQ at 553. Nor does the possibility of independent discovery relieve Suzuki of liability:

"[S]ecret formulas and processes * * * are property rights which will be protected by injunction, not only as against those who attempt to disclose or use them in violation of confidential relations or contracts express or implied, but as against those who are participating in such attempt with knowledge of such confidential relations or contract, though they might in time have reached the same result by their own independent experiments or efforts."

Id. at 167, 329 P.2d at 153, 118 USPQ at 553-54 (quoting *Herold v. Herold China & Pottery Co.*, 257 F. 911, 913 (6th Cir.1919)). Indeed, Suzuki did not argue that it had actually developed on its own the information that it first received from Richardson. Although Richardson adduced evidence that Suzuki had been unable to solve this problem, it is not relevant what Suzuki might have been able to do on its own. Ninth Circuit law upholds trade secret status even had the same information been obtainable from other sources. *Clark v. Bunker*, 453 F.2d 1006, 1010, 172 USPQ 420, 423 (9th Cir.1972) (trade secrecy "is not negated because defendant by an expenditure of effort might have collected the *1244 same information from sources available to the public.") (footnote omitted).

[23] The court also erroneously instructed the jury that "slavish" copying is necessary for misappropriation, and that an exercise of independent judgment would remove the information from protection. The court instructed the jury to consider: "Were they secrets. And, second, did the defendants slavishly use them or did they make up their own minds." These views are contrary to California law. "[D]efendants cannot escape responsibility by showing that they have improved upon or modified the plaintiff's process." *By-Buk Co.*, 163 Cal.App.2d at 169, 329 P.2d at 154, 118 USPQ at 554. The court observed in *Sinclair v. Aquarius Electronics, Inc.*, 42 Cal.App.3d 216, 222, 116 Cal.Rptr. 654, 659, 184 USPQ 682, 684 (1974) that minor variations are to be expected.

Suzuki argued to the jury, and repeats on appeal, that information that Richardson developed after issuance of the '332 patent, including the Alternate Shock Mount, is barred from trade secret status because it was generally disclosed in Richardson's patent or known to the general public, or because it merely implements the patented invention.

[24][25] The legal status of information and improvements made after a patent application has been filed is independent of the presence, or absence, of the patent application or ensuing patent. The information and improvements may be separately patentable; they may be preserved in confidence and disclosed only in accordance with agreement; and they are protected against misappropriation in accordance with the laws of contract and tort. The court misstated the law in telling the jury that the jury could decide whether Richardson could have both a valid patent and legal protection for later-developed information on the patented invention:

So on the one hand [Richardson] says the ordinary person skilled in the art can take this patent and use it and make a machine based upon it. But, on the other hand, he says, however, the experimentation and the ability to do this constitutes trade secrets for which you must pay me. Now, that constitutes a dilemma and it's up to you to

determine the extent to which Mr.

Richardson may claim as trade secrets things that the ordinarily prudent person skilled in the art should be able to do on his own.

The district court's phrase "should be able to do on his own" may explain its misperception of the law. It is not known what Suzuki was able to do on its own, for Suzuki not only sought Richardson's knowhow, improvements, data, and information, but also agreed to respect the confidentiality thereof. This information is intellectual property in the eyes of the law, and is protected in accordance with law. See generally *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 493, 94 S.Ct. 1879, 1892, 40 L.Ed.2d 315 (1974). See also *Components for Research, Inc.*, 241 Cal.App.2d at 730, 50 Cal.Rptr. at 832 (whether the product design was patented or not, plaintiff is entitled to trade secret protection for manufacturing process); *Sinclair*, 42 Cal.App.3d at 225, 116 Cal.Rptr. at 660, 184 USPQ at 686 ("Trade secret law encourages invention in areas where patent law does not reach"). *Accord Thermotics, Inc. v. Bat-Jac Tool Co., Inc.*, 541 S.W.2d 255, 261, 193 USPQ 249, 253 (Tex.Civ.App.1976) (post-patent improvement protectable under trade secret law); *Franke v. Willschek*, 209 F.2d 493, 495, 99 USPQ 431, 433 (2d Cir.1953) (immaterial that defendants could have derived trade secrets from expired patent).

It is apparent that the court imposed a higher standard for trade secret status than is contained in California law. The court's instructions, commentary, and phrasing of the special verdicts not only placed a prejudicially heavy burden on Richardson, but also demeaned the information itself.

Despite this prejudicial environment, the jury found that items 5 and 6 were trade secrets and had been misappropriated by Suzuki, and assessed damages therefore. The jury also found that items 1-4 and 7-11 were not trade secrets, and that for some but not all of these items compensation*1245 should be awarded based on "benefit from the plaintiff's knowledge and from the time and effort expended by him".

The district court granted Suzuki's motion for a new trial with respect to items 5 and 6, and upheld the jury verdicts with respect to items 1-4 and 7-11.

C. The new trial of items 5 and 6

[26] The grant of a new trial is ordinarily not reviewable, but on this issue the district court entered final judgment for purposes of appeal, and certified three questions. The first certified question is:

1. Were the plaintiff's asserted trade secrets Nos. 5 and 6: (a) Actually valid proprietary trade secrets, as the jury found and awarded very substantial royalties; or (b) Did the plaintiff's contributions in these respects represent no more than the services of a skilled mechanic, which readily could have been duplicated by the defendant, and which entitled the plaintiff only to quantum meruit compensation, as the court believes; or (c) Were the plaintiff's contributions no more than those contemplated under the option agreement and paid for by the defendant, as the defendant contends?

We respond to this question: From the record before us the jury verdict that items 5 and 6 met the requirements for trade secret protection was supported by the great weight of the evidence. Richardson and Cazort testified about the design modifications that were the subject of item No. 5 and the Alternate Shock Mount subject of item No. 6. The Alternate Shock Mount was considered sufficiently novel and valuable that Suzuki included it in a patent application filed in Japan and later in the United States. The record does not negate the jury's determination of the value of this information. According to California law it is immaterial what Suzuki could have done, for it chose to use Richardson's information, which it obtained under restraint.

[27] In further response, we remark that the relation between the parties, set by contract, was a routine commercial arrangement wherein Richardson agreed to facilitate Suzuki's testing and evaluation of Richardson's invention. This did not convert Richardson's work in adapting his invention to

Suzuki's motorcycle into the work of a hired technician whose work product was automatically owned by Suzuki. The proprietary nature of the work done and information provided by Richardson was established by agreement, as was the agreement that Suzuki would not use this information if it did not exercise its option.

There was substantial evidence before the jury that the information on items 5 and 6 was not publicly known, that Suzuki agreed to receive and preserve it in confidence, and that the information fully satisfies the statutory and jurisprudential requirements for protectible trade secrets.

In order to vacate the jury's verdict upholding items 5 and 6 as trade secrets and grant a new trial thereon, the trial court must find that the jury's verdict "is contrary to the clear weight of the evidence, or is based upon evidence which is false, or to prevent, in the sound discretion of the trial judge, a miscarriage of justice." *Hanson v. Shell Oil Co.*, 541 F.2d 1352, 1359 (9th Cir.1976), *cert. denied*, 429 U.S. 1074, 97 S.Ct. 813, 50 L.Ed.2d 792 (1977) (quoting *Moist Cold Refrigerator Co. v. Lou Johnson Co.*, 249 F.2d 246, 256, 115 USPQ 160, 168-69 (9th Cir.1957), *cert. denied*, 356 U.S. 968, 78 S.Ct. 1008, 2 L.Ed.2d 1074 (1958)); *William Inglis & Sons Baking Co. v. ITT Continental Baking Co., Inc.*, 668 F.2d 1014, 1027 (9th Cir.1981), *cert. denied*, 459 U.S. 825, 103 S.Ct. 57, 74 L.Ed.2d 61 (1982). It is insufficient that the district court would simply have reached a different verdict.

Our review requires determination of whether the district court abused its discretion in its decision to grant the new trial. *Id.* See *Transgo, Inc. v. Ajac Transmission Parts Corp.*, 768 F.2d 1001, 1014, 227 USPQ 598, 602 (9th Cir.1985), *cert. denied*, 474 U.S. 1059, 106 S.Ct. 802, 88 L.Ed.2d 778 (1986) ("the grant or denial of either a motion for a new trial or a motion to amend the judgment must be reviewed on the basis of a determination of whether the district court abused its discretion.") *1246 See generally *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 756 F.2d 1574, 1581, 225 USPQ 357, 363 (Fed.Cir.1985)

("Abuse of discretion may be established by showing that the district court either made an error of law, or a clear error of judgment, or made findings which were clearly erroneous.") The district court's statements, for example with respect to item 5, "I simply cannot conclude that that is a trade secret. It was an attempt to help Suzuki adapt the Richardson concept to the Suzuki machine ...", reflect an error of law.

Despite the legal error in the instructions, as we have discussed, any prejudice resulting therefrom favored Suzuki, not Richardson. We conclude that the district court exceeded its discretionary authority in vacating the jury verdict and ordering a new trial. That action is reversed, and the jury verdict is reinstated as to items Nos. 5 and 6, including the damages assessed for items Nos. 5 and 6.

D. Items 1-4 and 7-11

[28] For asserted trade secrets Nos. 1-4 and 7-11, the jury may well have been led by erroneous instructions into applying an incorrect legal standard, in finding that these items were not trade secrets. It appears, however, that Richardson did not move for judgment n.o.v. or a new trial on these verdicts. Although there is a hint in the post-trial colloquy that the court intended or was willing to retry all the trade secret issues along with items 5 and 6, this does not satisfy the rule, supported by logic, that the formalities of post-trial motions be respected. *Snellman v. Ricoh Co.*, 836 F.2d 528, 534, 5 USPQ2d 1341, 1346 (Fed.Cir.1987) (applying Ninth Circuit law in holding that motions for judgment n.o.v. and for a new trial must be made). Thus we have no authority to review these verdicts.

By special verdict the jury was also asked to assess damages for Suzuki's use of the information encompassed in each of items 1-4 and 7-11, even if the information did not "rise to the dignity of trade secrets". The jury determined this sum for each item, some at \$0, the highest at \$25,000, for a total of \$104,000. The district court sustained this award, on a theory of "quantum meruit

compensation". Both parties appeal this award, Richardson asserting its inadequacy, and Suzuki arguing that Richardson was fully paid for his information in the option agreement, and is not entitled to damages for Suzuki's use of any information received from Richardson.

We have rejected, as a matter of law, Suzuki's theory that it is entitled to use, free, the information disclosed by Richardson under the option agreement. Richardson's disclosures were made under terms that prohibited their use by Suzuki if the option was not exercised. This contract provision does not depend on whether the information is a trade secret, but only on whether it was previously known to Suzuki or generally known to the public, as discussed *ante*.

[29] An appellate tribunal is abjured to determine whether a jury verdict can be sustained, on any reasonable theory. *Jaffke v. Dunham*, 352 U.S. 280, 281, 77 S.Ct. 307, 308, 1 L.Ed.2d 314 (1957) ("A successful party in the District Court may sustain its judgment on any ground that finds support in the record.")

[30] There was substantial evidence at trial whereby a reasonable jury could have determined the sums awarded by this jury. Indeed, Suzuki does not challenge the valuations of the damage awards for items 1-11, arguing instead that nothing at all is owing.

The judgment as to items 1-4 and 7-11 is affirmed, including damages assessed for these items in the total amount of \$104,000.

V Injunction

The district court, having entered final judgment that the Suzuki Full Floater suspension infringed claim 9 of the '332 patent, denied Richardson's motion for injunction.

Infringement having been established, it is contrary to the laws of property, of *1247 which the patent law partakes, to deny the

patentee's right to exclude others from use of his property. 35 U.S.C. § 261. "[T]he right to exclude recognized in a patent is but the essence of the concept of property". *Connell*, 722 F.2d at 1548, 220 USPQ at 198 (citing *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed.Cir.1983)).

[31][32] It is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281, 6 USPQ2d 1277, 1283 (Fed.Cir.1988). Suzuki has presented no such reason. This court stated in *H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390, 2 USPQ2d 1926, 1929-30 (Fed.Cir.1987), when reviewing an injunction granted *pendente lite*:

In matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement. *Smith International*, 718 F.2d at 1581, 219 USPQ at 692. This presumption derives in part from the finite term of the patent grant, for patent expiration is not suspended during litigation, and the passage of time can work irreparable harm.

We observe that the '332 patent will expire in less than four years, that litigation started over eight years ago, and that the district court remarked that further proceedings could consume "several years".

[33] Further, a misappropriator of trade secrets has no authorization of right to continue to reap the benefits of its wrongful acts. Richardson is entitled to an injunction against Suzuki's continuing use of trade secrets Nos. 5 and 6. *By-Buk Co.*, 163 Cal.App.2d at 167, 329 P.2d at 153, 118 USPQ at 553-54; *Components for Research, Inc.*, 241 Cal.App.2d at 730, 50 Cal.Rptr. at 832.

The denial of Richardson's request for injunction is reversed. On remand the district court shall enter appropriate injunctive relief.

VI Fraud

The jury found by special verdicts that Suzuki fraudulently induced Richardson to reveal his trade secrets by concealing its intention not to exercise its option or take a license, and that Suzuki fraudulently concealed from Richardson the fact that it was developing the Full Floater "with the intention of declining to exercise the option and then nevertheless to utilize the plaintiff's trade secrets in the full floater". The jury also found fraud in that Suzuki filed the Tamaki patent application "in the knowledge that the invention asserted therein (the spring/swing arm connection) was first disclosed to them by Richardson". The jury awarded Richardson \$20,000 in compensatory and \$100,000 in punitive damages.

The district court vacated the judgment and ordered a new trial. Suzuki asserts that the court should have granted Suzuki's motion for judgment n.o.v. instead of ordering a new trial, while Richardson asserts that the court should have upheld the jury verdicts.

The district court certified the question of how to treat its belief that Suzuki did not commit the offenses of fraud and concealment found by the jury, including the question of punitive damages. We first must consider whether a reasonable jury could have reached the verdicts here reached. *Lavender v. Kurn*, 327 U.S. at 653, 66 S.Ct. at 744. Apt is the statement of the Ninth Circuit in *Crocker-Citizens Nat'l Bank v. Control Metals Corp.*, 566 F.2d 631, 635 (9th Cir.1977): "Courts are not free to reweigh the evidence and set aside the jury verdict merely because the jury could have drawn different inferences or conclusions or because judges feel that other results are more reasonable", quoting *Cockrum v. Whitney*, 479 F.2d 84, 86 (9th Cir.1973), in turn quoting *Tennant v. Peoria & P.U. Ry. Co.*, 321 U.S. 29, 35, 64 S.Ct. 409, 412, 88 L.Ed. 520 (1944).

[34][35] The record shows that there was testimony, based on certain of Suzuki's documents, on which a reasonable jury *1248 could have supported these verdicts. There were issues of credibility, and inferences that could reasonably have been drawn in a manner adverse to Suzuki. "The credibility of

witnesses and the weight of the evidence are issues for the jury and are generally not subject to appellate review." *Benigni*, 853 F.2d at 1525. While the district court may have believed that Suzuki did not commit fraud, review shows that the requirements for vacating the jury verdicts and relitigating the issue were not met. *Hanson*, 541 F.2d at 1359; *William Inglis*, 668 F.2d at 1027. A fresh trial is not warranted simply because the district court would have reached a different verdict.

[36] A jury assessment of punitive damages is not excluded in circumstances such as those here presented, where the jury expressly found fraud. *Tri-Tron Int'l v. Vello*, 525 F.2d 432, 437, 188 USPQ 177, 181 (9th Cir.1975) ("where compensatory damages are sought and awarded, the court has power, on a proper record, to award punitive damages"), citing *Clark v. Bunker*, 453 F.2d 1006, 1012, 172 USPQ 420, 424 (9th Cir.1972), in turn citing *El Rancho, Inc. v. First Nat'l Bank*, 406 F.2d 1205, 1218 (9th Cir.1968), *cert. denied*, 396 U.S. 875, 90 S.Ct. 150, 24 L.Ed.2d 133 (1969) (jury verdict awarding punitive damages was supported by evidence of malice) and *Davenport v. Mutual Benefit Health & Accident Ass'n*, 325 F.2d 785, 787 (9th Cir.1963) (remand for trial to allow evidence of fraud to support claim of punitive damages.)

The district court correctly instructed the jury as to the law, stating that "it's only if you find that the defendants' conduct stem from malice, oppression, fraud or bad faith that you can find any punitive damage at all." As stated in *In re Innovative Construction Systems, Inc.*, 793 F.2d 875, 889, 230 USPQ 94, 104 (7th Cir.1986):

[A] breach of faith underlies every trade secret claim. However, establishing that breach alone is insufficient to warrant an award of punitive damages; one must also demonstrate that the defendant acted wantonly, willfully, or in reckless disregard of the plaintiff's rights. (Citations omitted)

See also *Neal v. Farmers Insurance Exchange*, 21 Cal.3d 910, 928, 582 P.2d 980, 986, 148 Cal.Rptr. 389, 395 (1978) ("In order to justify an award of exemplary damages, the defendant must be guilty of oppression, fraud

or malice. (Civ.Code § 3294.) He must act with the intent to vex, injure or annoy, or with a conscious disregard of the plaintiff's rights") (quoting *Silberg v. California Life Insurance Co.*, 11 Cal.3d 452, 462, 521 P.2d 1103, 1110, 113 Cal.Rptr. 711, 718 (1974)); *Reynolds Metals Co. v. Lampert*, 316 F.2d 272, 275 (9th Cir.1963), *cert. denied*, 376 U.S. 910, 84 S.Ct. 664, 11 L.Ed.2d 608 (1964) (in jury trial, evidence to justify punitive damages must show injury was done maliciously or willfully and wantonly or committed with bad motive or recklessly); *Transgo, Inc.*, 768 F.2d at 1024 (The determination to award punitive damages was "within the exclusive province of the jury") (quoting *Runge v. Lee*, 441 F.2d 579, 584, 169 USPQ 388, 392 (9th Cir.), *cert. denied*, 404 U.S. 887, 92 S.Ct. 197, 30 L.Ed.2d 169 (1971)).

The jury having found by special verdicts that Suzuki acted fraudulently, the requisite intent was established. "We give the trial judge and jury wide discretion in assessing punitive damages." *Hatrock v. Edward D. Jones & Co.*, 750 F.2d 767, 772 (9th Cir.1984). The jury's award was not "so disproportionate to the damages sustained as to be the result of passion or prejudice". *Id.* (citing *Neal*, 21 Cal.3d at 928, 582 P.2d at 990, 148 Cal.Rptr. at 399). *Transgo, Inc.*, 768 F.2d at 1024 ("We will not overturn such an award unless it appears that the jury was influenced by passion or prejudice.") (citing *Harmsen v. Smith*, 693 F.2d 932, 947 (9th Cir.1982), *cert. denied*, 464 U.S. 822, 104 S.Ct. 89, 78 L.Ed.2d 97 (1983)).

We answer the certified question that, in this case, neither a new trial nor judgment n.o.v. was warranted. The order of a new trial on this issue is vacated. The judgment on the jury verdicts of fraud and the award of compensatory and punitive damages is reinstated.

***1249 VII**
The Tamaki Patent

Richardson states that Suzuki fraudulently patented the Alternate Shock Mount that had been disclosed to Suzuki by Richardson and

Cazort, in a patent that also described the "criss-cross" modification developed at Suzuki. There was evidence and argument on the factual premises, including the absence of supporting documentation on the part of the named inventors Hirohide Tamaki and Manabu Suzuki, the earliest record on their behalf being dated October 1979. The corresponding Japanese patent application was filed on October 16, 1979.

The jury rendered the following special verdicts:

C-3. Did Suzuki and/or Mr. Tamaki file the Tamaki patent application in the knowledge that the invention asserted therein (the spring/swing arm connection) was first disclosed to them by Richardson:

Answer: YES

H-1. Do you find that the Plaintiff, Richardson, is the real inventor of the invention shown in the Tamaki patents and patent applications?

Answer: NO

It was not significantly disputed at trial that claims 1 through 8 of the Tamaki corresponding United States Patent No. 4,457,393 cover the Alternate Shock Mount of Richardson and Cazort, and that claim 9 includes the criss-cross embodiment of Tamaki and Suzuki. (The scope of claim 5 is raised, but is not material to our conclusion.)

[37] The district court denied Richardson's post-trial motion that the Tamaki patent be assigned to Richardson. In colloquy with counsel the court explained that it could not do so because "the jury said Richardson wasn't the inventor". Indeed it was conceded, and discussed at trial, that Richardson and Cazort, not Richardson alone, invented the Alternate Shock Mount. Cazort, as well as Richardson, testified at length on this structure. Special verdict H-1 that Richardson is not "the real inventor" is in accord with the co-inventor status of Cazort, and also with the Japanese contribution of the criss-cross embodiment.

The force of special verdict C-3 is not diminished. This verdict was not challenged on appeal. "It was further the duty of the

court to direct the appropriate judgment to be entered upon the special verdict." *Traders and General Insurance Co. v. Mallitz*, 315 F.2d 171, 175 (5th Cir.1963). The district court having failed to implement this verdict, Richardson's motion for judgment and for assignment of the Tamaki patents was not out of order.

[38] The remedy of assignment of the Tamaki patents is a different question from whether Richardson is a sole or joint inventor. The correction of inventorship is an administrative step, and is not before the court. Similarly, the presence of a further modification in one or two claims of the patent directed to the Alternate Shock Mount does not negate the imposition of an equitable remedy. To hold otherwise would ratify and indeed reward the wrongdoing.

Based on the jury verdict, Richardson is entitled to ownership of the patents as against Suzuki. Such remedy is appropriate under the circumstances; *see, e.g., Colgate-Palmolive Co. v. Carter Products, Inc.*, 230 F.2d 855, 865, 108 USPQ 383, 391 (4th Cir.), *cert. denied*, 352 U.S. 843, 77 S.Ct. 43, 1 L.Ed.2d 59 (1956) (corporate assignee of patent application ordered to assign to original holder of trade secrets all rights to patent applications based thereon); *De Long Corp. v. Lucas*, 176 F.Supp. 104, 134 (S.D.N.Y.1959), *aff'd*, 278 F.2d 804 (2nd Cir.), *cert. denied*, 364 U.S. 833, 81 S.Ct. 71, 5 L.Ed.2d 58 (1960) (when an employee has acquired patents on inventions developed by his former employer, "the courts will hold the wrongdoer to be a constructive trustee of the property misappropriated and will order a conveyance by the wrongdoer to the former employer"); *Becher v. Contoure Laboratories, Inc.*, 279 U.S. 388, 49 S.Ct. 356, 73 L.Ed.2d 752 (1929) (same); *Saco-Lowell Shops v. Reynolds*, 141 F.2d 587, 598, 61 USPQ 3, 13 (4th Cir.1944) (requiring assignment of patent *1250 based on ideas received by licensee from licensor in confidence during development of invention for market).

[39] Suzuki argues that Richardson has no remedy other than by seeking an interference in the United States Patent and Trademark Office with his own invention, and presumably

by taking similar actions, if such are available, in other countries. We do not agree. The courts are not powerless to redress wrongful appropriation of intellectual property by those subject to the courts' jurisdiction.

The denial of Richardson's motion for judgment is reversed. Suzuki shall assign to Richardson the patents filed by Suzuki that include the Richardson/Cazort invention of the Alternate Shock Mount, in all countries. We remand to the district court for the purpose of implementing compliance.

VIII Prejudgment Interest

The district court denied Richardson's request for prejudgment interest on both the patent infringement and the trade secret damage awards. Prejudgment interest is the rule governing this class of award. *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 655, 103 S.Ct. 2058, 2062, 76 L.Ed.2d 211, 217 USPQ 1185, 1188 (1983); *Lummus Industries, Inc. v. D.M. & E. Corp.*, 862 F.2d 267, 274, 8 USPQ2d 1983, 1988 (Fed.Cir.1988); *Fromson*, 853 F.2d at 1573-74, 7 USPQ2d at 1611; *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 807 F.2d 964, 967, 1 USPQ2d 1191, 1193 (Fed.Cir.1986), *cert. denied*, 482 U.S. 915, 107 S.Ct. 3187, 96 L.Ed.2d 675 (1987).

No exceptional circumstances having been shown, and no reason why damages for misappropriated trade secrets should be treated differently from damages for patent infringement, the denial of prejudgment interest is reversed.

IX Willful Infringement and Exceptional Case

The district court refused to submit the question of willful infringement to the jury, stating that Richardson had not provided sufficient evidence to go to the jury.

To refuse to give an issue to the jury is to direct a verdict in favor of the opposing party. Thus we review the district court's ruling on

the standard of "whether the evidence permits only one reasonable conclusion after viewing the evidence in the light most favorable to the non-moving party and drawing all inferences in favor of that party." *Bulgo v. Munoz*, 853 F.2d 710, 714 (9th Cir.1988) (citing *Peterson v. Kennedy*, 771 F.2d 1244, 1256 (9th Cir.1985), *cert. denied*, 475 U.S. 1122, 106 S.Ct. 1642, 90 L.Ed.2d 187 (1986)). See also *Connell*, 722 F.2d at 1546, 220 USPQ at 197.

[40] Richardson refers to the evidence adduced in connection with the jury verdicts of fraud, to the verdicts of misappropriation of trade secrets 5 and 6, to the absence of any opinion of United States counsel concerning validity of the '332 patent when Suzuki started its infringing activity, and to evidence from Suzuki's records tending to show bad faith. Viewing this evidence in the light most favorable to Richardson, and drawing all reasonable inferences in his favor, there was sufficient evidence to take to the jury, for the evidence does not require a verdict in favor of Suzuki. Absent sufficient basis for directing the verdict, Richardson has the right of jury determination of this factual question. Willfulness of behavior is a classical jury question of intent. *Shiley*, 794 F.2d at 1568, 230 USPQ at 115; *Hammerquist v. Clarke's Sheet Metal, Inc.*, 658 F.2d 1319, 1325-26, 212 USPQ 481, 486 (9th Cir.1981), *cert. denied*, 460 U.S. 1052, 103 S.Ct. 1499, 75 L.Ed.2d 930 (1983). When trial is had to a jury, the issue should be decided by the jury.

We remand for this purpose. The jury's findings on the issue of willfulness will be pertinent not only to the question of multiplication of damages under 35 U.S.C. § 284, but also to determination of whether this is an exceptional case in terms of 35 U.S.C. § 285. Entitlement under California *1251 Civil Code § 3426 et seq. may also be considered.

X Other Arguments

Both sides have raised many points in their briefs, disputing most aspects of the proceedings. We have considered all

arguments in reaching our conclusions.

Costs

The award by the trial court of only one third costs to Richardson, in view of the judgments in his favor on the major substantive issues, exceeded the trial court's discretionary authority. Richardson is entitled to his statutory costs incurred before the district court. The reduction thereof is reversed.

Costs on this appeal are taxed in favor of Richardson.

AFFIRMED IN PART, REVERSED IN
PART, VACATED IN PART, AND
REMANDED

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